Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study of the Effectiveness of Trans-diagnosis With Relaxation Therapy on Psychological Symptoms, Parental Beliefs About Neonatal Intensive Care Unit, Adaptation to Mother Role and Social and Occupational Adjustment in Parents of Premature Neonates Admitted to Neonatal Intensive Care Unit

Protocol summary

Study aim

A Comparative of the Effectiveness of Trans-diagnosis With Relaxation Therapy on Psychological Symptoms, Parental Beliefs About Neonatal Intensive Care Unit (NICU), Adaptation to Mother Role and Social and Occupational Adjustment in Parents of Premature Neonates Admitted to Neonatal Intensive Care Unit (NICU)

Design

A clinical trial with a control group, with parallel, randomized groups, on 36 parents, will use the quadratic randomized blocking method for randomization.

Settings and conduct

The study population in this study will include all parents whose infants were admitted to the Neonatal Intensive Care Unit (NICU) in 2020. The sample of this study will be selected from all parents whose infants are hospitalized in the Neonatal Intensive Care Unit (NICU) of hospitals affiliated to Shiraz University of Medical Sciences. To conduct this research, after the approval of the ethics committee of Kermanshah University of Medical Sciences and its registration in the clinical trial (IRCT), hospitals affiliated to Shiraz University of Medical Sciences will be referred.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: having a baby admitted to the neonatal intensive care unit (NICU) Main exclusion criteria: Absence from two sessions of treatment sessions

Intervention groups

18 participants will receive Trans-diagnosis treatment (experimental group) and 18 participants will receive a booklet and CD of relaxation techniques (control group).

Main outcome variables

depression, anxiety, emotional regulation strategies, self-compassion, parental beliefs about neonatal intensive care unit (NICU), adaptation to mother role, work and social adjustment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160103025817N5**
Registration date: **2020-11-25, 1399/09/05**
Registration timing: **prospective**

Last update: **2020-11-25, 1399/09/05**
Update count: **0**

Registration date

2020-11-25, 1399/09/05

Registrant information

Name

Ali Akbar Parvizi Far

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date
2021-02-19, 1399/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study of the Effectiveness of Trans-diagnosis With Relaxation Therapy on Psychological Symptoms, Parental Beliefs About Neonatal Intensive Care Unit, Adaptation to Mother Role and Social and Occupational Adjustment in Parents of Premature Neonates Admitted to Neonatal Intensive Care Unit

Public title
A Comparative Study of the Effectiveness of Trans-diagnosis With Relaxation Therapy on Psychological Symptoms, Parental Beliefs About Neonatal Intensive Care Unit, Adaptation to Mother Role and Social and Occupational Adjustment in Parents of Premature Neonates Admitted to Neonatal Intensive Care Unit
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Premature baby survival The baby is single Conscious desire and satisfaction of parents to participate in research If the mother is a participant in the study, she should not be hospitalized at the same time Non-abuse of drugs, alcohol and psychotropic drugs, and other drugs (based on participants' comments) Non-development of chronic mental disorders and personality disorders structured according to the principles of the clinical interview Have a minimum cycle education Scoring higher than the cut-off point in the Beck Depression and Anxiety Inventory Not receiving other psychological services at the same time
Exclusion criteria:
Failure to answer the questions of the questionnaires used in the research (at least 5% of the questions in each questionnaire) Absence from two sessions of treatment Unwillingness to continue the process of any of the treatments
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will first be selected by purposive sampling method and then will be assigned to the four groups using a random quadratic blocking method. The participants are divided into four blocks (9 people in each block). In this method, usually, the number of people assigned to each group is almost equal and blocks are formed based on the desired variables, and within each block, half of the people are involved and half are considered as controls. The main purpose of this method is to balance the number of participants in each group. The four blocks of the intervention groups (A) and control (B) will be defined (AABB, ABAB, ABBA, BBAA, BABA, BAAB) and will be written on the number cards 1 to 6. The cards are then placed in an envelope. Finally, the cards are randomly selected and a random string is created from the sequence of selected cards. The participants of the intervention and control group enter the research based on this sequence.
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 Kermanshah University of Medical Sciences
Street address
Kermanshah, Shahid Beheshti Blvd., Building No. 2, University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2020-11-10, 1399/08/20
Ethics committee reference number
IR.KUMS.REC.1399.809

Health conditions studied

1

Description of health condition studied
depression
ICD-10 code
F33.1
ICD-10 code description
Major depressive disorder, recurrent, moderate

2

Description of health condition studied
anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
bepression score in Beck Inventory
Timepoint
Pre-test, post-test and follow-up
Method of measurement
Beck Depression Inventory

2

Description
anxiety score in Beck Inventory
Timepoint
Pre-test, post-test and follow-up
Method of measurement
Beck Anxiety Inventory

3

Description
score emotion regulation strategies
Timepoint
pre-test, post-test, follow-up
Method of measurement
emotion regulation Gross and John questionnaire

4

Description
self-compassion score
Timepoint
pre-test, post-test and follow-up
Method of measurement
self-compassion questionnaire

5

Description
score of parents' beliefs about the neonatal intensive care unit
Timepoint
pre-test, post-test and follow-up
Method of measurement
Questionnaire of parents' beliefs about neonatal intensive care unit

6

Description
score of adaptation to mother role (For mothers)
Timepoint
pre-test, post-test and follow-up
Method of measurement
questionnaire of adaptation to the mother role

7

Description
score work and social adjustment
Timepoint
pre-test, post-test and follow-up
Method of measurement
work and social adjustment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The structure of meta-diagnostic treatment sessions will be based on Barlow (2011) model, which includes 8 sessions of 90 minutes and will be performed weekly. The structure and techniques of each session will be as follows: Session 1: Psychological training and motivation to treat emotional problems, Session 2: Emotional awareness training, Sessions 3 and 4: Correction of cognitive assessments, Sessions 5 and 6: Emotionally influenced behaviors and Emotional Avoidance, Sessions 7 and 8: Situational and Endogenous Exposure.
Category
Behavior

2

Description
Control group: Participants in this group will receive a training booklet and relaxation technique CDs on a scheduled basis. At first, practical training will be provided to them by a trained specialist. They will then be given a booklet and CD of relaxation training. This treatment is performed by the participants themselves at home. The time required to perform this training does not take more than 5-7 minutes at a time.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Zeinabiyyeh Hospital of Shiraz
Full name of responsible person
Dr. Reza Bahrami
Street address
Shiraz-Holy Defense Intersection-Hazrat Zeinab Therapeutic Training Center

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2

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
دانشگاه علوم پزشکی کرمانشاه
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Participants are not yet known.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available