# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effect of a Trauma-Informed Mobile-Based Education-Support Program Compared with Usual Care on Stress, Anxiety, and Maternal Self-Efficacy among Mothers of Preterm Infants

## Protocol summary

**Study aim**

To determine the effect of a trauma-informed mobile-based education and support program, compared with usual care, on parental stress, anxiety, and perceived maternal self-efficacy among mothers of preterm infants hospitalized in the neonatal intensive care unit.

**Design**

Randomized, two-arm, parallel-group clinical trial of 60 mothers (30 per group), with 1:1 block randomization using blocks of four and concealed allocation; statistical analysis will be blinded.

**Settings and conduct**

Randomized clinical trial with two parallel groups, 60 mothers (30 per group), block randomization with blocks of four at a 1:1 ratio, unblinded participants, and a blinded data analyst; trial phase not applicable.

**Participants/Inclusion and exclusion criteria**

Participants/Inclusion and Exclusion Criteria ـ English Key inclusion criteria: Mothers of preterm infants born at less than 37 weeks of gestation; infant hospitalized in the neonatal intensive care unit for at least 72 hours at the beginning of the study; maternal age of 18 years or older; ability to read and write; access to a smartphone and ability to use WhatsApp or telephone communication; written informed consent. Key exclusion criteria: Major congenital anomalies, genetic disorders, or severe neurological disorders in the infant; critical and unstable clinical condition of the infant; severe psychiatric disorders or cognitive impairment in the mother; lack of access to a smartphone.

**Intervention groups**

Intervention Groups Intervention group: Receiving a trauma-informed mobile-based education and support program for 4 consecutive weeks, comprising educational text content, audio guidance files, and supportive messages via a mobile messenger, in addition to routine neonatal intensive care unit care.

**Main outcome variables**

Maternal stress, anxiety, and self-efficacy at the end of the fourth week of the intervention

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20251020067698N4**
Registration date: **2026-08-26, 1405/06/04**
Registration timing: **prospective**

Last update: **2026-08-26, 1405/06/04**
Update count: **0**

**Registration date**

2026-08-26, 1405/06/04

**Registrant information**

**Name**

Sara Kord

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2026-09-22, 1405/06/31

**Expected recruitment end date**

2026-10-24, 1405/08/02

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of a Trauma-Informed Mobile-Based Education-Support Program Compared with Usual Care on Stress, Anxiety, and Maternal Self-Efficacy among Mothers of Preterm Infants

**Public title**
Effect of a Trauma-Informed Mobile-Based Education-Support Program on Mental Health of Mothers of Preterm Infants
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Being the mother of a preterm infant born at less than 37 weeks of gestation The infant having been hospitalized in the neonatal intensive care unit for at least 72 hours at the beginning of the studyBeing at least 18 years oldHaving the ability to read and write Having a smartphone and access to WhatsApp or telephone communication Willingness to participate in the study and signing the written informed consent form Not having a severe mental illness or cognitive impairment that could affect cooperation
**Exclusion criteria:**
The infant having a major congenital anomaly The infant having a known genetic disorder The infant having a severe neurological disorder The infant having a critical and unpredictable medical condition at the initial assessment Lack of access to a smartphone or inability to use WhatsApp or telephone communication The mother being unable to read and write The mother having a severe mental illness or cognitive impairment that could prevent study completion or effective cooperation Unwillingness to participate in the study or refusal to sign the written informed consent form
**Age**
From **18 years** old
**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**
Participants will be allocated to the intervention and control groups using blocked randomization. Permuted blocks of four will be used with a 1:1 allocation ratio between the be performed control groups. The unit of randomization will be the individual eligible mother, and allocation will be performed at the individual level. No stratified randomization will be used in this study. The randomization sequence will be generated using statistical software by a person independent of the intervention implementation team, preferably a statistician. After completion of the pretest, group allocation will be performed using sequentially numbered, sealed, opaque envelopes. The contents of the envelopes will remain concealed from the researcher and the participant until the time of allocation. Due to the educational nature of the intervention, blinding of the participants and the interventionist will not be possible. However, the statistical analysis will be conducted by a statistician who will be unaware of the participants' group assignments.
**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 Dezful University of Medical Sciences
**Street address**
Central Building, Dezful University of Medical Sciences, Payam-e Noor Blvd., Dezful
**City**
Dezful
**Province**
Khouzestan
**Postal code**
۶۴۶۱۶۴۳۹۴۳
**Approval date**
2026-07-23, 1405/05/01
**Ethics committee reference number**
IR.DUMS.REC.1405.052

## Health conditions studied

**1**

**Description of health condition studied**
Stress and Anxiety in Mothers of Preterm Infants
**ICD-10 code**
P00.5
**ICD-10 code description**
Newborn (suspected to be) affected by maternal injury

## Primary outcomes

**1**

**Description**
Maternal stress score measured using the Parental Stressor Scale: Neonatal Intensive Care Unit (PSS:NICU) before the intervention and four weeks after the intervention.

**Timepoint**
Before the intervention and four weeks after the end of the intervention

**Method of measurement**
Parental Stressor Scale for the Neonatal Intensive Care Unit

**2**

**Description**
Maternal anxiety score measured using the State-Trait Anxiety Inventory (STAI) before the intervention and four weeks after the intervention

**Timepoint**
Before the intervention and four weeks after the end of the intervention

**Method of measurement**
Spielberger State-Trait Anxiety Inventory

**3**

**Description**
Maternal self-efficacy score measured using the Perceived Maternal Self-Efficacy Scale (PMSE) before the intervention and four weeks after the intervention

**Timepoint**
Before the intervention and four weeks after the end of the intervention

**Method of measurement**
Perceived Maternal Self-Efficacy Scale

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: A 4-week trauma-informed mobile-based supportive educational program delivered via smartphone (WhatsApp or similar messaging platform). The program includes daily notifications, text/audio/visual educational content, a digital emotion journal, and researcher responses to educational and supportive questions during specified daily hours. Content is designed based on trauma-informed care principles (safety, trustworthiness, choice, collaboration, empowerment, and cultural sensitivity) and is structured weekly as follows:Week 1 (Familiarization and recognition of trauma responses): Education on traumatic reactions after preterm birth and NICU admission, postpartum anxiety, and recording feelings in a digital journal.Week 2 (Creating safety): Familiarization with the NICU environment, deep breathing and relaxation techniques (audio files), and reducing feelings of loss of control.Week 3 (Empowerment): Education on preterm infant care (touch therapy, feeding, interpreting infant behavioral cues), enhancing maternal self-efficacy, and positive mother-infant interaction.Week 4 (Discharge preparation): Home care plan, warning signs, personal care planning, and ongoing support.In addition to mobile content, an initial 20–30-minute face-to-face session is conducted by the researcher on the first day of study entry to introduce the program and the NICU environment. Daily 5–10-minute follow-ups, teach-back assessment of understanding, and empathic support using the NURSE framework in cases of severe anxiety are provided. After post-test completion, the educational content is provided to the control group for educational equity.Control group: Routine NICU care. This includes general and usual information about the infant's condition provided by the shift healthcare staff (nurse or responsible physician). No structured educational package, audio files, digital journal, daily notifications, or planned educational sessions similar to the intervention group are provided.

**Category**
Behavior

**2**

**Description**
Control group:Routine and usual care provided in the Neonatal Intensive Care Unit (NICU) of Dr. Ganjavian Hospital, Dezful. This includes general and day-to-day information about the infant's clinical condition given by the shift healthcare staff (responsible nurse or physician) according to the standard unit protocol. Mothers in this group do not receive any structured educational package, educational audio files, digital emotion journal, daily notifications, trauma-informed mobile-based content, planned educational sessions, or regular supportive responses from the researcher. After completion of the post-test phase and to ensure educational equity, the full educational-supportive program content will also be provided to the mothers in the control group.

**Category**
Behavior

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Dr. Ganjavian Hospital

**Full name of responsible person**
Mohammad Danehchin

**Street address**
Dr. Ganjavian Hospital, Opposite the 292nd Armored Brigade, Dezful-Andimeshk Road, Dezful, Khuzestan Province, Iran

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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Dezfoul University of Medical Sciences
**Full name of responsible person**
Mohammad Amin Bahmanesh
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Post Street, Corner of Dadgostari Street, 15 Khordad Boulevard, Dezful, Khuzestan Province, Iran
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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**
Dezfoul 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**
Dezfoul University of Medical Sciences
**Full name of responsible person**
Mohammad Danehchin
**Position**
Master of Science Student in Nursing
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Bachelor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Due to the thesis-based and single-center nature of the study, limited resources, and the requirements of the Ethics Committee of Dezful University of Medical Sciences regarding the protection of participants' privacy and confidentiality, there is no plan to share individual participant data (IPD). Data will only be reported at the group level in a summarized form in the final thesis report and any related publications.
**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