

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the Effect of an Educational Intervention on Discharge Readiness of Preterm Infant's Parents

Protocol summary

Study aim

To determine the effect of an educational intervention on discharge readiness of preterm infants' parents

Design

Two arm parallel group non randomized controlled trial, discharge education intervention with outcome parents readiness assessment

Settings and conduct

The place of the study Muhumbili and Mloganzila National Hospitals, Dar es Salaam; The study population Parents of Preterm Infants.

Participants/Inclusion and exclusion criteria

Parents of preterm infants with a gestational age of less than 37 weeks; Parents are the main caregivers of preterm infants after discharge from the hospital; Being literate (at least elementary school education and above) parents of preterm infants; Parents with at least 18 years of age; Home as the child's discharge destination; Parents, who are mentally stable and in fair condition based on parent self-report and review of their medical records by the researcher. Exclusion Criteria Parents of preterm infants with congenital anomalies; Those neonates who need major operation; neonates who are readmitted to the hospital;

Intervention groups

Intervention group: Parents in the intervention group will receive four sessions of discharge's educational intervention. Each session will last for 60 minutes; the researcher will use lecture, questions and answers, using videos demonstration and discussion as the method of teaching the participants. After each session premature infants' parents will be given handout about the teaching for memorizing. Control group: Parents in the control group will only receive normal hospital discharge routine care.

Main outcome variables

Readiness score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231015059726N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Glory Masimango

Name of organization / entity

Country

Tanzania, United Republic of

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of an Educational Intervention on Discharge Readiness of Preterm Infant's Parents

Public title

Discharge Intervention on Readiness of Parents

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents of preterm infants with a gestational age of less than 37 weeks Parents are main caregivers of preterm infants after discharge from hospital Literate (at least elementary school education and above) parents of preterm infants Parents with at least 18 years of age Home as the child's discharge destination Parents, who are mentally stable and in fair condition based on parent self-report and review their medical records by researcher 24 hours post-delivery at intervention medical center or 48 hours post admission in NICU or HDU from peripheral hospitals

Exclusion criteria:

Parents of preterm infants with congenital anomalies Those who need major operation Who are readmitted to the hospital

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

this will be a random assignment between two hospitals, in which one hospital will be randomly assigned to be the control hospital and the other hospital will be assigned to be the intervention hospital.

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

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Mirkhani(nosrat) St; Tohid sq.

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Approval date

2023-10-15, 1402/07/23

Ethics committee reference number

IR.TUMS.FNM.REC.1402.143

Health conditions studied**1****Description of health condition studied**

The current study is relevant to neonates health improvement, by conducting a program that prepare parents for neonates discharge.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Parents Readiness for Discharge. In this study we will use PedRHDS form for Parents of Hospitalized Children (including NICU) that consist of 29 (23) items in 5 subscales including: Parent Personal status = 1a,2a,3a,4a,5a,6fa, 6b,7a (8 items); (items 2a, 5a, 6b should be reverse scored), Child Personal status = 1b,2b,3b,4b,5b (5 items): (item 2b should be reverse scored), Knowledge = 8 to 16 (9 items), Coping Ability = 17-19 (3 items) and Expected Support = 20-23 (4 items). Scores are calculated by adding item scores and dividing by the number of items, thus calculating the RHDS score as the mean of item scores. The possible range of scores is 0 to 10 using this method. This approach applies to total scale and subscale scores.

Timepoint

one week after intervention.

Method of measurement

The data will be gathered by using questionnaire (PedRHDS form).

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention will involve conducting four face-to-face educational sessions with a duration of one hour for each session, that will be conducted every other day. The educational intervention will consists of providing

information regarding the care for a pre-term new born after discharge(including Kangaroo Mother Care, feeding, safe sleeping positions, thermal care, bathing, diaper changing, vaccination, general hygiene, and follow-up clinics).

Category

Other

2**Description**

Control group: The control group receive normal hospital routine (some information regarding the neonates feeding, and other consideration will be provided for parents during the discharge, in some cases this procedure maybe missed).

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Muhimbili National Hospital

Full name of responsible person

Dr. Mehrnaz Geranmayeh

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2**Recruitment center****Name of recruitment center**

Mloganzila National Hospital in Tanzania, Africa

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

No grant

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

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**

Tehran University of Medical Sciences

Full name of responsible person

Marzieh Hasanpour

Position

Supervisor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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

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