

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The Effect of Educational & Supportive Relactation Program on Weight Gaining of Preterm Infants in Neonatal Intensive Care

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Summary

This is a quasi-experimental study which was performed in NICU of Alzahra hospital in Tabriz from Apr 20 to November 5th, 2011. Sixty premature infants with low birth weight were studied. Both the control and intervention groups involved 30 samples. The appropriation of these two groups for the infants was non-random and simple by sampling where at first the control group and then the intervention group were specified regarding the probability of information transferring and contacting between mothers. The control group infants received the routine trainings of the ward for relactation from the nurses. The trainings were sporadic, done in less time and without enough follow-up. But the experimental group received the supportive training of relactation in an organized procedure in addition to the routine trainings mentioned above. This procedure included: recommending taking the prescribed pills consistently, consuming more liquid and protein-rich foods, using electrical or hand pumping for each breast every 2 or 3 hours for 15 to 20 minutes, and performing KMC twice a day each time at least for 60 minutes. The supportive acts in the experimental group were performed through the following steps: 1. Creating an appropriate training environment 2. The nursing support was provided by a trained researcher 3. Consulting the mothers was performed face to face and individually and daily. Both groups were followed for 14 days. The frequency of breastfeeding and feeding with formula, KMC and daily weight were measured and recorded in the information collecting form by the co-researcher who wasn't informed about the type of infants' group.

Last update:

Update count: **0**

#### Registration date

2013-04-21, 1392/02/01

#### Registrant information

##### Name

Sousan Valizadeh Dehkharghani

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

009804134751706- 34796770

##### Email address

valizades@tbzmed.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Tabriz University of Medical Sciences

#### Expected recruitment start date

2012-04-21, 1391/02/02

#### Expected recruitment end date

2013-09-01, 1392/06/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201304044613N10**

Registration date: **2013-04-21, 1392/02/01**

#### Scientific title

The Effect of Educational & Supportive Relactation Program on Weight Gaining of Preterm Infants in Neonatal Intensive Care

#### Public title

The Effect of Relactation Program on Weight Gaining of Preterm Infants

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion Criteria for infants: immature infants under 2 months, hospitalized in nursery or NICU) without congenital anomalies or nervous problems, cardio - vascular hereditary diseases and injuries during labor, who had not contraindication for breast feeding - single baby. Criteria for mothers: mothers with infants under 2 months - decreased the mother's milk and more than half of infant breast feeding is provided by supplementary feeding - mothers who had not feeding her baby at least a week and a maximum of four weeks. Mothers had with stable physical and mental condition and willing to breast feeding of their baby - in the mother's breast examination there are not any breast problems such as abscesses, systemic diseases, mastitis, depressed nipples shall interfere with breastfeeding. Exclusion criteria for infants: contraindicated breastfeeding during intervention period - diagnosis of neurological problems, cardiovascular disease and congenital anomalies in infants during intervention period. Exclusion criteria for mothers: lack of cooperation for breastfeeding.

## Age

To 2 years old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Preterm

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences , Gholghasht St.

## City

Tabriz

## Postal code

## Approval date

2011-05-01, 1390/02/11

## Ethics committee reference number

5/4/1133

## Health conditions studied

### 1

#### Description of health condition studied

Neonatal difficulty in feeding at breast

#### ICD-10 code

P92.5

#### ICD-10 code description

Neonatal difficulty in feeding at breast

## Primary outcomes

### 1

#### Description

Weight Gaining of preterm infant

#### Timepoint

1- 14

#### Method of measurement

Ska digital devices for infant

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

infants in control group receives routine training, includes recommendations for Shyrafza drugs (metoclopramide Vshyrafzay plant), breast milk pUmping by hand or pump your KMC By Nursing Staffs.

#### Category

Other

### 2

#### Description

infants of experimental group in addition to the routine training, recieved educational support program that includes Supportive-educative relactition program includes recommendations for regular doses of prescription pills →, more fluid and protein foods, keep using the hand pump or electric 3-2 hours for 20-15 minutes every breast and KMC regularly 2 times a day for at least 60 minutes. and daily encouragement and Fallowup by the one of researcher . Supportive exercises in this groups includes: 1) creating a conducive environment for learning (training in relactation rooms and an evening shift was part of the training was to prepare the mother calmly). 2) supported by a trianed

nurse (give data in relation to relactition to mothers).

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Nahid Dekhoda

**Street address**

Alzahra hospital , Baghshomal Square, Artesh St.

**City**

Tbriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Parviz Shahabi

**Street address**

Nursing & Midwifery Faculty, Shariaty St.

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Nahid Dekhoda

**Position**

NICU Master degree Nursing student

**Other areas of specialty/work**

**Street address**

Tabriz Nursing & Midwifery Faculty

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51668-44199

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n.dekhoda@gmail.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*