Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between Yakson and Gentle HumanTouch on behavioral states of preterm infants hospitalized in the neonatal intensive care units

Protocol summary

Summary

Preterm infants hospitalized in neonatal intensive care units (NICU) are exposed to numerous stressors. Appropriate touching stimulations helped the growth and development of preterm infants by alleviating stress. This study is conducted to compare the effect of Yakson and Gentle Human Touch (GHT) on preterms' behavioral states in NICU in South-East of Iran. Yakson is a Korean touching method for healing and relaxation similar to GHT. An experimental study design is used. Ninety preterm infants (26–34 weeks gestational age) (Yakson group, n=30; GHT group, n=30; control group, n=30) participated in this study who are admitted to neonatal intensive care units in Afzli pour hospital. The Yakson and GHT groups each receive an intervention for 15 min twice a day for 5 days while the control group receives usual nursing care. The behavioral state of preterm infants is evaluated by the Anderson Behavioral State Scale (ABSS) in 2 minute before initiation of interventions and 2 minute after that.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201163250N5**
Registration date: **2012-12-07, 1391/09/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-07, 1391/09/17

Registrant information

Name

Bahareh Bahman Bijari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2012-03-01, 1390/12/11

Expected recruitment end date

2012-05-30, 1391/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Yakson and Gentle HumanTouch on behavioral states of preterm infants hospitalized in the neonatal intensive care units

Public title

Effect of Yakson and Gentle Human Touch on preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: (1) a gestational age of 26–34 weeks at birth;(2) not having undergone surgery. Exclusion criteria: (1) congenital anomalies; (2) Apgar score less than 6 at 5 min; (3 Lack of medical condition contraindicating the running of Yakson or GHT such as symptomatic sepsis.

Age

From **26 years** old to **34 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences

Street address

Jahad Blvd, Ebn Sina Avenue

City

Kerman

Postal code

76198-13159

Approval date

2012-01-18, 1390/10/28

Ethics committee reference number

K/90/342

Health conditions studied

1

Description of health condition studied

preterm infant

ICD-10 code

P07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation

Primary outcomes

1

Description

Behavioral state

Timepoint

2 miniute befor intervention and 2 miniute after intervention

Method of measurement

Anderson Behavioral State Scale (ABSS)

Secondary outcomes

1

Description

Harte rate

Timepoint

2 miniute befor intervention and 2 miniute after intervention

Method of measurement

Spacelabs medica manitor

2

Description

Arterial oxygen saturation

Timepoint

2 miniute befor intervention and 2 miniute after intervention

Method of measurement

Spacelabs medica manitor

Intervention groups

1

Description

Yakson intervention: 1. After wearing a clean inner gown, the researcher washed her hands and arms thoroughly with antimicrobial agents for 3 min. 2. She warmed both of her hands using a radiant warmer until the temperature of the palms reached 93.2 8F (34.0 8C). 3. She relaxed both arms and the muscles of both shoulders for 1 min and breathed deeply to concentrate Ki energy on their palms. 4. She provided Yakson to preterm infants. Yakson lasted 15 min: hand resting (5 min), gentle caressing (5 min), and hand resting again (5 min). During the administration of Yakson, the palms and all fingers of the researcher constantly maintained close contact with the infants up to the limit that preterm infants did not feel pressure. (1) Hand resting (5 min): while resting one hand on the chest and abdomen of a preterm infant while supporting the back of the preterm infant with the other hand, the researcher concentrated on her resting hands and envisioned that a healthy Ki was passing to the preterm infant. At that time, the researcher breathed slowly to maintain a relaxed state. (2) Gentle caressing (5 min): in the same hand position, the researcher repeated caressing and resting for 5 min; caressing (1 min) – resting (30 s) – caressing (1 min) – resting (30 s) – caressing (2min). The researcher caressed the infant’s chest and abdomen clockwise in a

1 cm diameter circular motion every 10 s. (3) Hand resting (5 min): researcher followed the same hand resting procedure as described above.

Category

Other

2

Description

GHT intervention: The Gentle Human Touch (GHT) protocol was as follows: Jay (1982) and Harrison et al. (2000). 1. After wearing a clean inner gown, the NICU nurses trained washed both hands and arms with antimicrobial agents for 3 min. 2. The NICU nurses trained warmed both of her hands using a radiant warmer until the temperature of the palms reached 93.2 8F. 3. For 15 min, the NICU nurses trained placed the fingertips of one hand above the eyebrow line with the palm touching the preterm infant's crown while the other hand was rested on the lower abdomen of the infant encompassing the waist and the hip.

Category

Other

3

Description

Control group: receive routine nursing care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzali por Educational Center, Kerman University of Medical Sciences

Full name of responsible person

Fateme Eshghi, MSc student of NICU

Street address

Afzali por Educational Center, Emam Highway

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences

Full name of responsible person

Dr. Reza Malek Pour Afshar

Street address

Jahad Blvd, Ebn Sina Avenue

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology, Kerman 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

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Bahareh Bahman Bijari

Position

Associate Professor/neonate subspecialist

Other areas of specialty/work

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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