

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of listening to the Holy Quran recitation on the time for transition from gavage to the first oral feeding, weight gain, and the length of hospital stay of preterm infants in the neonatal intensive care unit

Protocol summary

Study aim

Determining the listening to the Holy Quran recitation on the time for transition from gavage to the first oral feeding, weight gain, and the length of hospital stay of preterm infants

Design

The present study of a randomized clinical trial type with a control group, a blind, randomized, on 64 infant.

Settings and conduct

Intensive care unit of the kosar hospital in Qazvin city. The infants were in the supine position then specialized headphones were individually fitted for each infant and positioned correctly on their ears. For participants in the intervention group, a recitation from the Holy Quran comprising verses 78 to the end of Surah Al-Isra was played at an intensity of 45 decibels. The neonatologist, nurses and parents of the infants will also be blinded in the study groups.

Participants/Inclusion and exclusion criteria

obtaining parental consent for the infant's participation, possessing normal hearing, stable vital signs over the past 12 hours, overall clinical stability, and achieving an Apgar score of ≥ 7 in the first and fifth minutes after birth. The exclusion criteria: any manifestation of stress-related symptoms during the intervention, the necessity for therapeutic or care interventions during the study, and any decrease in the level of consciousness.

Intervention groups

The infants were in the supine position then specialized headphones were individually fitted for each infant and positioned correctly on their ears. For participants in the intervention group, a recitation from the Holy Quran comprising verses 78 to the end of Surah Al-Isra was played at an intensity of 45 decibels. The participants listened to the Holy Quran recitation three times a day, lasting for a duration of 10-20 minute.

Main outcome variables

the infant's weight gain; duration of hospitalization of the infant, duration of the mother's pregnancy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220409054461N2**

Registration date: **2024-03-16, 1402/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-16, 1402/12/26**

Update count: **0**

Registration date

2024-03-16, 1402/12/26

Registrant information

Name

Seyed Reza Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 66 3320 0894

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-10, 1402/12/20

Expected recruitment end date

2024-04-08, 1403/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of listening to the Holy Quran recitation on the time for transition from gavage to the first oral feeding, weight gain, and the length of hospital stay of preterm infants in the neonatal intensive care unit

Public title

The effect of listening to the Holy Quran recitation on the time for transition from gavage to the first oral feeding, weight gain, and the length of hospital stay of preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

obtaining parental consent for the infant's participation possessing normal hearing no history of neurological or cognitive abnormalities no head-related injuries stable vital signs over the past 12 hours overall clinical stability achieving an Apgar score of ≥ 7 in the first and fifth minutes after birth. infants had to be fed with either breast milk or formula.

Exclusion criteria:

involved any manifestation of stress-related symptoms during the intervention the necessity for therapeutic or care interventions during the study decrease in the level of consciousness

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be performed experimentally and randomly in two groups of test and control. For this purpose, a table of random numbers is used. In this way, the researcher will first determine that all the people to whom the odd number is assigned to be in the control group and those to whom the even number is assigned to be in the test group. He will then close his eyes and place his finger on one of the digits in the random number table. The researcher will select the required number of even and odd numbers by moving in the table of random numbers. All numbers will be placed in separate envelopes and all will be placed in a box. When the sample enters the study easily with the entry

conditions, then the number one card will be returned to him and depending on whether this card has an even or odd number will be in one of two test or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will include two groups including the intervention and control group, which will be conducted among preterm infants. The selection of persons to enter the study will be made on the infants of the criteria for entering the study and upon receipt of written consent from their parents. People entering the study will be randomly simplified into two groups of equal numbers. In this study, infant doctors, nurses and parents of infants will also be blinded in study groups. It should be explained that the intervention, data collection and data entry will also be carried out by the researcher himself.

Placebo

Not used

Assignment

Other

Other design features

The study will include two groups including the intervention and control group, which will be conducted among preterm infants. The selection of persons to enter the study will be made on the infants of the criteria for entering the study and upon receipt of written consent from their parents. People entering the study will be randomly simplified into two groups of equal numbers.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin, Shahid Bahner Boulevard, the campus building of the University

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2024-01-20, 1402/10/30

Ethics committee reference number

IR.QUMS.REC.1402.321

Health conditions studied

1

Description of health condition studied

Infants, children, nursing, the sound of the Qur'an

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the time for transition from gavage to the first oral feeding

Timepoint

before the intervention and 3 days after the intervention

Method of measurement

Number of days based on the calendar

2

Description

The amount of weight gain that the scale shows

Timepoint

before the intervention and 3 days after the intervention

Method of measurement

Seca weight digital scale with an accuracy of ± 10 grams

3

Description

length of hospitalization of premature infants

Timepoint

before the intervention and 3 days after the intervention

Method of measurement

The number of days based on the infants document

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention was conducted during the evening shifts between 14:00 and 20:00, leveraging the quieter atmosphere of the ward during this time. The infants were first placed in a nest in the supine position and then connected to monitors by the responsible nurses. Specialized headphones were individually fitted for each infant and positioned correctly on their ears. If an infant showed agitation during this process, the headphones were temporarily removed and repositioned after a short interval. It should be noted that, in order to prevent the effects of headphones, they were placed on the ears of the infants in both groups. For participants in the intervention group, a recitation from the Holy Quran comprising verses 78 to the end of Surah Al-Isra was played at an intensity of 45 decibels. This level of sound was carefully calibrated to both adhere to safe sound ranges and effectively mask ambient noise.

The participants listened to the Holy Quran recitation three times a day, lasting for a duration of 10-20 minutes, starting three days after the initiation of gavage feeding until they transitioned to their first oral feeding.

Category

Other

2

Description

Control group: No sound will be played for participants in the control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Seyed Reza mousavi

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College of Nursing and Midwifery, Shaheed Bahonar Blvd., Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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

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Qazvin, Shahid Beheshti Boulevard, Maudet Alley

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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

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Farnoosh Rashvand

Position

faculty member

Latest degree

Ph.D.

Other areas of specialty/work

nursing

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Qazvin University of Medical Sciences

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Seyed Reza Mousavi

Position

Master of psychiatric nursing

Latest degree

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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

Not applicable

Data Dictionary

Not applicable