Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 of10-20 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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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 if 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
Street address
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
Street address
Qazvin, Shahid Beheshti Boulevard, Maudet Alley
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Email
research.dpt@qums.ac.ir
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
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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