Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of sole reflex massage and Yakson's touch on behavioral reactions and weighing of premature babies

Protocol summary

Study aim
Comparison of the effect of sole reflex massage and Yakson's touch on behavioral reactions and weighing of premature babies

Design
The samples will be randomly assigned to two intervention groups (foot reflex massage and Yakson touch) and a control group.

Settings and conduct
The researcher will start sampling by referring to Amirkabir Arak Hospital and Neonatal Special Care Department. Yakson touch (5 minutes of rest-5 minutes of gentle stroking-5 minutes of rest) and foot massage will be performed for 15 minutes each and twice a day (8 am and 8 pm). In a day, two massage sessions should be done up to 5 days. Every 5 days, the weight of the babies will be recorded by the nurse at the beginning of the morning shift. Behavioral reactions will be checked twice at 8 am before the intervention and at 8 pm after the intervention. all three groups receive routine treatment in the neonatal intensive care unit.Blinding is in the form of a blind. The statistician is blind.

Participants/Inclusion and exclusion criteria
Entre: Babies with a gestational age of 26-34 weeks Having a stable clinical and physiological condition in a hospitalized baby Having a 5th minute Apgar score of 7 or higher Birth weight 1500-2499 grams No congenital abnormalities Absence of the baby's mother's addiction to cigarettes and drugs Feeding the baby only with breast milk Failure to enter: Having a medical condition prohibiting the implementation of Yaxon, such as an unstable clinical condition Perform surgery Parents' unwillingness to continue the intervention Receiving painkillers to relieve the baby's pain in the last 24 hours

Intervention groups
foot reflexology massage - Yakson touch

Main outcome variables
Behavioral reaction score based on Anderson's behavioral reaction scoring system Weight

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240729062579N1**
Registration date: **2024-08-05, 1403/05/15**
Registration timing: **prospective**

Last update: **2024-08-05, 1403/05/15**
Update count: **0**

Registration date
2024-08-05, 1403/05/15

Registrant information
Name
Leila Rahimi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-22, 1403/06/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of sole reflex massage and Yakson's touch on behavioral reactions and weighing of premature babies

Public title
The effect of sole reflex massage and Yakson's touch on the behavior and weight of premature babies

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Babies with a gestational age of 26-34 weeks Having a stable clinical and physiological condition in a hospitalized baby Having a 5th minute Apgar score of 7 or higher Birth weight 1500-2499 grams No congenital abnormalities Absence of the baby's mother's addiction to cigarettes and drugs Feeding the baby only with breast milk

Exclusion criteria:
Having a medical condition prohibiting the implementation of Yaxon, such as an unstable clinical condition Perform surgery Parents' unwillingness to continue the intervention Receiving painkillers to relieve the baby's pain in the last 24 hours

Age
From **7 days** old to **29 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **61**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, sampling of hospitalized babies who meet the entry criteria will be done using the available method. Then, the samples will be randomly divided into two intervention groups (foot reflex massage and Yakson touch) and a control group. In order to make a simple randomization in allocating people to each of the groups under study, a coded list of hospitalized infants whose informed consent was obtained from their parents and who meet the criteria for entering the study was prepared and then entered into the SPSS software with a random selection command. People will be allocated in three groups

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding will be done in a single-blind manner through a statistical analyst (statistical consultant). Patients will receive the intervention, and patients and nurses will be aware of the intervention performed on each group and the results, and the statistical analyst will be blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Sardasht-Arak University of Medical Sciences

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2024-06-29, 1403/04/09

Ethics committee reference number
IR.ARAKMU.REC.1403.121

Health conditions studied

1

Description of health condition studied
Behavioral reactions and weighing of premature babies

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Behavioral reactions - Anderson Behavioral Reactions Scoring System (ABSS) will be used in this study. This scale determines the behavioral status of the baby based on regular observations of breathing, eye opening or closing, body and trunk activity, and crying intensity.

Timepoint
Twice a day - once before the intervention and again after the intervention

Method of measurement
The research assistant evaluates the behavioral reactions of the babies 2 minutes before the intervention and leaves the research environment and re-evaluates the reactions of the babies 2 minutes after the intervention.

2

Description
Baby's weight

Timepoint
Every day at 8 am after feeding and changing diapers

and before the intervention for 5 days with a calibrated scale.

Method of measurement

Early in the morning using a baby digital scale - weight gain is presented as daily weight gain (g/day), cumulative weight gain (g) and growth rate (g/kg/day).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: foot reflex massage and Yakson touch - one person will be responsible for the intervention (researcher) and one person will be responsible for measuring the behavioral reactions and weighing the baby (ward nurse). In the foot reflexology intervention group, the researcher will gently massage the soles of the feet using gentle but firm pressure of the fingers and thumb. The combination of massage therapy in this study includes tactile and movement stimulation. The massage will be performed for 15 minutes and includes three periods of 5 minutes of tactile stimulation, followed by 5 minutes of motor stimulation and again 5 minutes of tactile stimulation.In a day, two massage sessions should be done up to 5 days. Massage pressure is adjusted to make the baby feel comfortable. The foot reflex massage intervention will be performed by a trained researcher under the same conditions and at a room temperature of 26 to 28 degrees Celsius twice a day (8 in the morning, 8 in the evening). Researcher Yakson's touch intervention in carrying out this intervention after wearing a clean He disinfects his hands and arms and then warms his hands with a warmer until the palms reach 34 degrees Celsius.In the next step, the researcher relaxes both arms and the muscles of both shoulders for one minute to concentrate the energy of the palms. In the last step, the researcher provides Yakson's touch to the premature baby. Yakson's touch will be performed for 15 minutes (according to the protocol). Foot reflex massage and Yakson's touch will be performed after the seventh day of hospitalization and the stabilization of the baby's physiological condition.

Category

Treatment - Other

2

Description

Control group - In the control group, only the usual nursing care of the newborn visa care department will be performed. The variables of the research will be measured in parallel with two intervention groups. The measurement of the behavioral reactions of the control group, like the two intervention groups, is done twice a day (8 in the morning and 8 in the evening) by the researcher's colleague.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Special Care Department of Amirkabir Hospital

Full name of responsible person

Leila Rahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak University of Medical Sciences

Proportion provided by this source

70

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
Arak University of Medical Sciences

Full name of responsible person
Leila Rahimi

Position
پرستار-کارشناسی ارشد پرستاری کودکان

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information such as the score of behavioral reactions of newborns, weight and sex of newborns, gestational age, first and fifth minute APCAR, birth grade, parents' occupation, parents' education, mother's age. Information will be published without mentioning names and personal details.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Only researchers working in academic and hospital institutions

Under which criteria data/document could be used
Under the condition of correct and ethical use in order to improve the care and refer to the information of this research and by preserving the rights of the researchers of this project

From where data/document is obtainable
Leila Rahimi rahimileila27@gmail.com

What processes are involved for a request to access data/document
Send name and surname - field of study - university of study - reason for needing said information - type of requested data - only via email

Comments