

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of TKS (Tactile Kinesthetic Stimulation) massage on physical growth of healthy infants

Protocol summary

Summary

The purpose of this study is to survey tactile kinesthetic stimulation massage effects on growth (weight, height, head circumference) in healthy infants. 70 infants will be considered; they are classified randomly into two groups: experimental (35 infants) and control (35 infants). Mothers completed the demographic questionnaire. This method in the experimental group will be done twice every day and each time for 15 minutes, for 4 continuous weeks. The first and third five minutes is for Tactile which includes top-down and rotational movements on the abdomen. The second 5 minutes is for Kinesthetic Stimulation that involves Leges adduction and abduction and Bicycle movements at the same time. The control group will receive any intervention in the same period. Two groups of infants, one day, term and healthy and eat only breast milk. Weight, height and head circumference of the infants measured at birth time, the end of 14th day and the end of 28th day. In the end, are compared both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608228348N35**

Registration date: **2016-10-16, 1395/07/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-16, 1395/07/25

Registrant information

Name

Neda Mirbagher

Name of organization / entity

Kashan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of TKS (Tactile Kinesthetic Stimulation) massage on physical growth of healthy infants

Public title

The effect of massage on physical growth of infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the one day infants weighing 4000-2500 grams, singleton, normal delivery, natural activity, appearance and color, the ability of breastfeeding, Apgar score above 7, no fetal malformations, Biographies after birth is normal, is terms, infant reflux is not severe. Exclusion criteria: blood transfusions, Incidence acute physical problems, changing dietary habits in infants during the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Using stratified random sampling

Secondary Ids

empty

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

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan, Ravand Street, Kashan University of Medical Sciences

City

Kashan

Postal code

8715981151

Approval date

2015-12-22, 1394/10/01

Ethics committee reference number

IR.KAUMS.REC.1394.117

Health conditions studied**1****Description of health condition studied**

massage

ICD-10 code

Z50

ICD-10 code description

Care involving use of rehabilitation procedures

Primary outcomes**1****Description**

Weight

Timepoint

Before intervention, after 2 weeks, after 4 weeks

Method of measurement

Balance grams

Secondary outcomes**1****Description**

Height and head circumference

Timepoint

Before intervention, after 2 weeks, after 4 weeks

Method of measurement

In centimeter using a tape measure

Intervention groups**1****Description**

Intervention group : Massage will be done twice every day and each time for 15 minute, for 4 continuous weeks. The first and third five minutes is for Tactile Stimulation on the abdomen. The second 5 minute, kinesthetic Stimulation in legs.

Category

Prevention

2**Description**

Control group: The control group will receive any intervention in the same period.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan beheshti and Shabihkhani hospital maternity ward

Full name of responsible person

Neda Mirbagher

Street address

Ravand, Parastar Street, Kashan University of Medical sciences

City

Kashan

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity
Vice chancellor for research of Kashan University of Medical Sciences

Full name of responsible person
Dr hamidi

Street address
Ravand,Parastar Street , Kashan University of Medical sciences

City
Kashan

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 of Kashan 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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Neda Mirbagher

Position
Ms

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

