

# 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, 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

mirbagher\_n@kaums.ac.ir

###### 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**

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Kashan University of Medical Sciences

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Neda Mirbagher

**Position**  
Ms

**Other areas of specialty/work**

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## Person responsible for updating data

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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*

