

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

the effect of massage with sunflower oil and sesame oil on crying, sleeping and infant growth

Protocol summary

Summary

The purpose of this study the effect of massage with sesame and sunflower oils long cry, sleep and infant growth. Study of a triple blind clinical trial that the group in order to compare the effects of massage with sunflower oil, sesame and massage alone on the duration of crying, sleep and growth of 120 infants will take 15 -10 days. Studied for 5 weeks, a week basis (to obtain basic information from the average duration of infant crying and sleep) and four weeks of the intervention will take. Mother Massage by 2 times (morning and afternoon) per day, each time for 15 minutes and 28 days (four weeks) is achieved. For crying, sleep duration, height and weight measurements and infants between the two groups will be compared. "

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102265912N1**

Registration date: **2012-01-08, 1390/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-08, 1390/10/18

Registrant information

Name

Mandana Mir Mohammad Ali Ei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

mirmohammad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-04-09, 1389/01/20

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of massage with sunflower oil and sesame oil on crying, sleeping and infant growth

Public title

massage with sunflower oil and sesame oil

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1) term infants (42-37) 2) 3 birth weight 4000-2500 g) singleton 4) fed exclusively with breast milk 5) absence of obvious disease or birth abnormalities 6) the first child of 7) minimal maternal Education in secondary school 8) lack of maternal diseases such as hypertension, diabetes, pregnancy, postpartum depression or any psychiatric illness related to maternal 9) no history of hospitalization due to disease, infant 10) lack of separation of infant from mother benchmarks withdrawal from the study: 1) sensitivity to any of the oils used for massage 2) disease public or skin infant during the study, 3) no intervention in four sessions consecutive or intermittent (48 h) 4) failure to complete the application form parents crying

baby for 24 hours at least 5) infant feeding with artificial milk, 6) NO mother's illness

Age

From **10 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Review Committee of Tehran University of Medical Sciences

Street address

Ghods street, Keshavarz BLD, Central building of Tehran Un

City

Tehran

Postal code

88987381

Approval date

2009-12-21, 1388/09/30

Ethics committee reference number

1388/130/1443

Health conditions studied

1

Description of health condition studied

crying ,sleep and Growth infant

ICD-10 code

z76.2

ICD-10 code description

Health supervision and care of other healthy infant and child

Primary outcomes

1

Description

crying

Timepoint

befor intervention-end the first week-end the the second week-End of the third week and the fourth week

Method of measurement

Daily form of crying parents

2

Description

sleep

Timepoint

befor intervention-end the first week-end the the second week-End of the third week and the fourth week

Method of measurement

Daily form of crying parents

3

Description

Weight

Timepoint

befor intervention-end the first week-end the the second week-End of the third week and the fourth week

Method of measurement

Standard Scales

4

Description

Height

Timepoint

befor intervention-end the first week-end the the second week-End of the third week and the fourth week

Method of measurement

Meter Standard

Secondary outcomes

empty

Intervention groups

1

Description

Massage with sunflower oil and sesame seeds in this study in order to massage with sunflower oil or sesame oil manufacturing company Baryj Essence Kashan was with 10 cc of oil twice a day every 15 minutes for 4 weeks doing be by the mother on the infant

Category

Other

2

Description

Control: In order to study without the use of massage oils

twice daily (morning and afternoon) every 15 minutes for 4 weeks will perform by mothers on infant

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center Number 1

Full name of responsible person

Ziba Raisi Dehkordi

Street address

Shahrekord

City

Malat Gharbi

2

Recruitment center

Name of recruitment center

Health Center Number 2

Full name of responsible person

Ziba Raisi Dehkordi

Street address

Shahrekord

City

Shahrekord

3

Recruitment center

Name of recruitment center

Health Center Number 9

Full name of responsible person

Ziba Raisi Dehkordi

Street address

Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Abass Hoshmand Bahabadi

Street address

Nosrat ST.Tohid SQ, Faculty of Nursing and Midwifery

City

Tehran

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, Tehran 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

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mandana Mirmohammadali

Position

Instructor

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mandana Mirmohammadali

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Person responsible for updating data

Contact

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Full name of responsible person

ziba Raisi Dehkordi

Position

Graduate Student

Other areas of specialty/work**Street address**

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Web page address

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

Data Dictionary

empty