

# 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**

Nosrat ST,Tohid Sq, Faculty of Nursing and Midwifery  
Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 6690 4252

**Fax**

**Email**

mirmohammad@tums.ac.i

**Web page address**

**Person responsible for scientific 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**

Nosrat ST,Tohid Sq, Faculty of Nursing and Midwifery  
Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 6690 4252

**Fax**

**Email**

mirmohammad@tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

ziba Raisi Dehkordi

**Position**

Graduate Student

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

Nosrat St, Tohid Sq, Faculty of Nursing and Midwifery

**City**

Tehran

**Postal code****Phone**

+98 381

**Fax****Email**

Raisid@tums.ac.ir

**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*