

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effects of Back Stroke Massage with Sesame Oil in Physiological Parameters and Hospitalization Anxiety in School- Age Girls in Pediatrics Medical Unit

Protocol summary

Summary

This study is an investigation of the influence of back stroking massage in physiological parameters and hospitalization anxiety in school- age girls. In this semi experimental study, 80 school age girls selected with available and sequential sampling and divided randomly in two groups (40 massage group and 40 controls). The samples were school -age girls and Iranian who had not any physical and mental disability and history of cardiac and kidney disease and exited from study if no physical and mental preparation for massage more than two times, discharging and death. The tools were demographic questionnaire and State-Trait Anxiety Inventory for Children. In intervention group, back stroking massage implemented for 3 days and 3 times every days and every session last 15 to 20 minutes. In second to forth days of hospitalization before sleeping (8 PM) and before and after of three days period in second to fifth days of hospitalization, hospitalization anxiety and physiological parameters have been determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205199798N1**

Registration date: **2013-07-03, 1392/04/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-03, 1392/04/12

Registrant information

Name

Manighe Nourian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Back Stroke Massage with Sesame Oil in Physiological Parameters and Hospitalization Anxiety in School- Age Girls in Pediatrics Medical Unit

Public title

The Effects of Massage in Physiological Parameters and Hospitalization Anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: School -age girls; Iranian and resident in Zahedan city; having not any physical and mental disability; having no history of mental disorders; having not history of cardiac and kidney disease, spinabifida,

skin allergy, epilepsy and cancer Exclusion criteria: No physical and mental preparation for massage more than two times; discharging of child and death

Age

From **9 years** old to **12 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences and Health Services

Street address

Kodakyar Avenue, Evin Highway, Tehran

City

Tehran

Postal code

1985717443

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

139001867633

Health conditions studied

1

Description of health condition studied

Hospitalization anxiety

ICD-10 code

f41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is)

Primary outcomes

1

Description

Hospitalization anxiety

Timepoint

Before and after 3 days period of hospitalization and before, duration and after of massage, 3 times a day for 20 minutes

Method of measurement

State- Trait Anxiety Inventory for Children

Secondary outcomes

1

Description

Respiratory rate, pulse rate, blood pressure rate

Timepoint

Before and after of three days period of hospitalization and before, during and after of massage, 3 times a day for 20 minutes

Method of measurement

Sphygmomanometer, inspection of respiratory rate and calculating of radial pulse rate

Intervention groups

1

Description

In massage group, back stroking massage was implemented for 3 times a day (10 AM, 3 PM and 7 PM) for 3 days (two to fourth days of hospitalization) and every session lasted 15 to 20 minutes. Massage started with circling movements of thumb finger and using of sesame oil from end of sternocleidomastoid to sacral region. This intervention continued 3 times. Mother of child presented during intervention.

Category

Prevention

2

Description

In control group presented researcher beside child and only hospitalization anxiety and physiological parameters assessed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliebne Abitaleb Hospital related to Zahedan University of Medical Sciences and Health Services

Full name of responsible person

Alieh Jalalodini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti Nursing and Midwifery College

Full name of responsible person

Amir Hosin Barbaz

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Valiasr Avenue, Niyayesh, Tehran

City

Tehran

Grant name

10506

Grant code / Reference number

123808

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti Nursing and Midwifery College

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

Nursing and Midwifery College, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Manighea Nourian

Position

Faculti member of science, Master of science in nursing, PhD student

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

Data Dictionary

empty