

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of aromatherapy with Narcissus flower and Lavender on anxiety and some vital signs of mothers of hospitalized children with burn

Protocol summary

Study aim

Determining and comparison of the effect of aromatherapy with Narcissus flower and Lavender on anxiety and some vital signs of mothers of hospitalized children with burn

Design

Parallel group randomized clinical trial in which participants will be divided in to 3 groups by permuted block randomization . Sample size was calculated 45.

Settings and conduct

All interested mothers of hospitalized children in Amiralmomenin burning hospital will be invited to participate in the study. Eligible participants enter the study. Participants are then randomly assigned to 3 groups. First, their anxiety level and vital signs will be measured and recorded. Then the intervention will be done. At the end, vital signs and anxiety will be measured again and compared with previous data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers of hospitalized burned children, able to read and write, negative history of allergy to aromatic substances, not using other methods for reducing anxiety, being able to talk and understand Persian 6-Not having olfactory disorders, negative history of migraine, cardiopulmonary disease or chronic mental disorder, not having severe activity, exercise, smoking or any factor effecting vital signs 30 minutes before checking vital signs, not taking drugs that affect vital signs
Exclusion criteria: Sudden allergic reactions, Worsening the child condition or child death, Note having desire to continue, Incomplete completion of the questionnaire

Intervention groups

Intervention groups will inhale 5 drops of Narcissus or Lavender essential oil poured on the gas at a distance of 10 cm from the nose for 15 minutes and the control group with the same condition will inhale odorless biter

almonds .

Main outcome variables

Vital signs(pulse, respiration, blood pressure), anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044347N4**

Registration date: **2021-08-04, 1400/05/13**

Registration timing: **prospective**

Last update: **2021-08-04, 1400/05/13**

Update count: **0**

Registration date

2021-08-04, 1400/05/13

Registrant information

Name

Fatemeh Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

shirazifa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aromatherapy with Narcissus flower and Lavender on anxiety and some vital signs of mothers of hospitalized children with burn

Public title

Comparison of the effect of aromatherapy with Narcissus flower and Lavender on anxiety and some vital signs of mothers of children with burn

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Mothers of burned hospitalized children Being able to read and write Not having allergy to aromatic substances Not using the other ways for reducing anxiety Being able to talk and understand Persian Not having olfactory disorder Negative history of migraine, cardiopulmonary disease or chronic mental disorder Not having severe activity, exercise, smoking or any factor affecting vital signs 30 minutes before checking vital signs Not taking drugs that affect pulse, respiration and blood pressure

Exclusion criteria:

sudden allergic reactions worsening the child condition or child death Not having desire to continue Incomplete completion of the questionnaire

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 45

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting eligible individuals to participate in the study, based on inclusion criteria, these individuals will be assigned to two study groups based on double randomized permutation block. The random list will be generated by a statistician using "Random Allocation" software.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz university of medical sciences, Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-07-07, 1400/04/16

Ethics committee reference number

IR.SUMS.REC.1400.355

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

Mothers of hospitalized children with burn

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger Anxiety Scale

2**Description**

Pulse

Timepoint

Before and after intervention

Method of measurement

Using digital blood pressure monitor

3**Description**

Blood pressure

Timepoint

Before and after intervention

Method of measurement

Using digital blood pressure monitor

4

Description

Respiratory rate

Timepoint

Before and after intervention

Method of measurement

Counting by researcher

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: Half to one hour before change dressing of burned children, the researcher will pour 5 drops of of Angostifolia lavender essential oil (100% concentration) on a piece of gas and the mothers of the children will hold that gas at a distance of about 10 cm from their nose and smell it for 15 minutes.

Category

Treatment - Other

2

Description

Half to one hour before change dressing of burned children, the researcher will pour 5 drops of of Narcissus essential oil (100% concentration) on a piece of gas and the mothers of the children will hold that gas at a distance of about 10 cm from their nose and smell it for 15 minutes.

Category

Treatment - Other

3

Description

Half to one hour before change dressing of burned children, the researcher will pour 5 drops of odorless bitter almond oil on a piece of gas and the mothers of the children will hold that gas at a distance of about 10 cm from their nose and smell it for 15 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin(AS) burn hospital

Full name of responsible person

Dr . Mohammad Mehdi Aslani

Street address

Sadra town

City

Shiraz

Province

Fars

Postal code

7198754361

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Abbas Rezaianzade

Street address

Vice-Chancellor for research, Shiraz University of Medical Science, Zand Blvd

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Shirazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Namazi Square,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Shirazi

Position

Assistant professor

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable