

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect of aromatherapy with roses and music therapy versus control group on anxiety level of patients who are candidate for elective general surgery: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the effect of aromatherapy with roses and music therapy versus control group on anxiety level of patients before elective general surgery Design: A randomized clinical trial. Setting and conduct: The eligible patients who are candidate for elective general surgery will refer to Kosar Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 54 years; candidate for elective general surgery; mental, verbal, visual, hearing and olfactory ability Exclusion criteria: Anxiety score more than 8 based on Beck anxiety test; cancer; receiving psychotropic, opioid, analgesic and sedative drugs; having pain before surgery, a history of allergy, asthma or allergic rhinitis Intervention group 1: Routine care plus playing instrumental music through headphone for 20 min. Intervention group 2: Routine care plus aromatherapy with roses for 10 min. Control group: Just routine care. Primary outcome: Assessing the anxiety level before and 30 min after intervention using standard Beck anxiety questionnaire. Randomization The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706089014N169**
Registration date: **2017-06-09, 1396/03/19**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-09, 1396/03/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Shiraz
University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aromatherapy with roses and music therapy versus control group on anxiety level of patients who are candidate for elective general surgery: a randomized clinical trial

Public title

Comparison of the effect of aromatherapy with roses and music therapy versus control group on anxiety level of patients who are candidate for elective general surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 54 years; candidate for elective general surgery; mental, verbal, visual, hearing and olfactory ability Exclusion criteria: Anxiety score more than 8 based on Beck anxiety test; cancer; receiving psychotropic, opioid, analgesic and sedative drugs; having pain before surgery, a history of allergy, asthma or allergic rhinitis

Age

From **18 years** old to **54 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Shiraz University of Medical Sciences, Zand Ave.

City

Shiraz

Postal code

Approval date

2017-05-20, 1396/02/30

Ethics committee reference number

IR.SUMS.REC.1396.28

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Assessing the anxiety level

Timepoint

before and 30 min after intervention

Method of measurement

using standard Beck anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Routine care plus playing instrumental music through headphone for 20 min.

Category

Other

2

Description

Intervention group 2: Routine care plus aromatherapy with roses for 10 min.

Category

Treatment - Drugs

3

Description

Control group: Just routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Hashem Rahmati

Street address

Kosar Hospital, Daneshgah Ave.

City

Sanadaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology, Shiraz
University of Medical Sciences

Full name of responsible person

Hashem Rahmati

Street address

Shiraz University of Medical Sciences, Zand Ave.

City

Shiraz

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 and Technology, Shiraz
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**

School of Nursing and Midwifery

Full name of responsible person

Hashem Rahmati

Position

MSc in Nursing

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

School of Nursing and Midwifery, Shahid Namazi Sq.

City

Shiraz

Postal code**Phone**

+98 71 3230 5410

Fax**Email**

H-Ramati1076@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Nursing and Midwifery

Full name of responsible person

Hashem Rahmati

Position

MSc in Nursing

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

School of Nursing and Midwifery, Shahid Namazi Sq.

City

Shiraz

Postal code**Phone**

+98 71 3230 5410

Fax**Email**

H-Ramati1076@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

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

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.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