Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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. RandomizationThe 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

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Name of organization / entity

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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
RandomizationThe 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
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Person responsible for updating data

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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