Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Progressive Muscle Relaxation Technique and Aromatherapy with Damask Rose on Anxiety, Stress and Depression in General Surgical Candidates

Protocol summary

Study aim
Compare the effect of relaxation and aromatherapy on the mental health of candidates for surgery

Design
Clinical trials with community based and pragmatic control group, with parallel groups, randomized

Settings and conduct
This intervention will be carried out in the surgery department of Kashani Hospital in Shahrekord. In the relaxation group, the questionnaire was completed by the researcher first. Then, on the day of the practice, the researcher selected his samples by referring to the general surgery department and trained the relaxation by transferring the patient to the place intended for training progressive muscle relaxation. . Then, one hour before the patient goes to the operating room, the patient listens with a handsfree audio file in the presence of the researcher. In the scent group, the questionnaire is first completed by the researcher. Then on the day of surgery one hour before going to the operating room, 3 drops of essential oil from the flower of Mohammadi are poured onto a tissue and pinned on the pillow of patients. There is no intervention in the control group.

Participants/Inclusion and exclusion criteria
The criteria for entering: 1. Patient of elective surgery 2- At least 18 and up to 60 years old. 3. Not having surgery history 4. The desire to cooperate 5- Hospitalization in the surgery section of the day before surgery Exit criteria : 1. Acute pain 2. Use of benzodiazepines 3. History of allergy 4- Death

Intervention groups
Progressive Muscle Relaxation Group Scent Therapy Group control group

Main outcome variables
Depression Anxiety Stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181122041720N1**
Registration date: **2018-12-06, 1397/09/15**
Registration timing: **prospective**

Last update: **2018-12-06, 1397/09/15**
Update count: **0**

Registration date
2018-12-06, 1397/09/15

Registrant information

Name
Shirin Madadkar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3338 2382

Email address
shirinmadadkar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-21, 1397/09/30

Expected recruitment end date
2019-03-19, 1397/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effect of Progressive Muscle Relaxation Technique and Aromatherapy with Damask Rose on Anxiety, Stress and Depression in General Surgical Candidates

Public title
Comparison of the Effect of Progressive Muscle Relaxation Technique and Aromatherapy with Damask Rose on Anxiety, Stress and Depression in General Surgical Candidates

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
1. The patient is on the list of elective general surgery (hernia and cholecystectomy). 2- Having at least 18 and up to 60 years old. 3- No history of surgery. 4- The desire to cooperate in research 5- Hospitalization in the surgery part of the day before surgery

Exclusion criteria:
1. Acute pain at the time of completing the questionnaire
2. Use of benzodiazepines and tranquillizers and opiates
3. History of allergy to plants 4. Death of the sick

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
After entering the study, the participants were randomly assigned to three groups using computer software using three blocks. To hide the assignment, the type of intervention was determined based on the blocking on the paper and placed inside the opaque packs of the sequential numbering. Envelopes were opened in the order of participation of the participants, and the specified intervention was implemented for the participants.

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
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Rahmatieh Shahrekord University of Medical Sciences

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Approval date
2018-03-02, 1396/12/11

Ethics committee reference number
SKUMS.REC.IR.1396.264

Health conditions studied

1

Description of health condition studied
Hernia

ICD-10 code
K40

ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Depression

Timepoint
Before intervention and immediately after intervention

Method of measurement
DASS questionnaire

2

Description
Anxiety

Timepoint
Before intervention and immediately after intervention

Method of measurement
DASS questionnaire

3

Description
Stress

Timepoint
Before intervention and immediately after intervention

Method of measurement
DASS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In the progressive muscle relaxant group, the questionnaire was completed by the researcher and the patient's vital signs were recorded by the researcher and recorded in the form. The intervention is done so that on the day of the work of the researcher, referring to the general surgery department of Kashani Hospital in Shahrekord, and reviewing the surgical list, select the samples and transferring the patient to the place intended for training progressive muscle relaxation, He teaches every person face-to-face and practical relaxation. Then, one hour before the patient goes to the operating room, by providing a completely quiet environment and minimizing environmental stimuli, such as low light of the room, and limiting travel to the patient's room, the patient through the hands-free program of progressive muscle relaxation audio in the presence of The researcher listens.In this method, the patient is placed in a comfortable comfortable bed. Closes his eyes and, as far as possible, stays in a state of relaxation and concentrates all his attention on his breathing. 5 times deep breath and each time the lungs completely fill the air and gently empty. Meanwhile, in his mind, he thinks relaxed and relaxed. After this stage, the patient should have muscle contraction and expansion for 14 muscle groups, including facial muscles (forehead, eyelids, jaws and lips), neck muscles, fingers and palms, forearm, arm, shoulder, back, Lumbar, chest, abdomen, seat, thighs, legs and legs. Each muscle contraction is 5 seconds and its expansion lasts 10 seconds. During the procedure, the patient should focus on the muscles that rigidify and relax. At the end, the patient relaxes his entire body, breathes deeply and lets his eyes slowly open and return to normal. The patient does this technique for 20 minutes (1). Then, the DASS questionnaire and the vital signs registration form are completed by the researcher.In the scent group, the questionnaires are first completed by the researcher and the patient's vital signs are recorded by the researcher and recorded in the relevant form. The intervention is then done on the day of operation one hour before going to the operating room, three drops of 10% essential oil from the flower of Mohammadi (made in Barij Essen, Kashan) will be poured onto a tissue paper and pinned on the pillow of the patients. And patients are asked to smell it for 20 minutes. According to previous studies, a tissue paper impregnated with three drops of essential oil of 10% may be produced for 12 hours (8 and 1). After the intervention, the DASS questionnaire and the vital signs registration form are completed by the researcher.Sampling in groups is done simultaneously.

Category

Other

2

Description

Control group: Control group: There is no intervention in the control group and all routine nursing care before the operation includes the patient's NPO, the location of the operation and the completion of the patient's case. In this group, the questionnaires were completed only one hour prior to going to the operating room and vital signs are recorded

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Shirin Madadkar

Street address

Nursing Street, Ayatollah Kashani Hospital

City

ShahreKord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816778915

Phone

+98 38 3226 4825

Email

Kashani@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Shahrekord University of Medical Sciences

Full name of responsible person

dr.Kamal Solati

Street address

Rahmatieh, Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3333 0061

Email

info@skums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Shahrekord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Shirin Madadkar

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing Street, Kashani Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816758915

Phone

+98 38 3226 4825

Email

Shirinmadadkar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Shirin Madadkar

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing Street, Kashani Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816758915

Phone

+98 38 3226 4825

Email

shirinmadadkar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Research Deputy of Shahrekord University of Medical Sciences

Full name of responsible person

Shirin Madadkar

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing Street, Kashani Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816759815

Phone

+98 38 3226 4825

Email

shirinmadadkar@gmail.com

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

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

Analytic Code

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

Data Dictionary

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