Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of music therapy and aromatherapy of chamomile-lavender on fatigue and anxiety of nurses working in Besat hospital of Sanandaj in 2018

Protocol summary

Study aim

: The effect of music therapy and aromatherapy of chamomile-lavender on fatigue and anxiety of nurses working in Besat hospital in Sanandaj in 2018

Design

The clinical trial was conducted in three groups of intervention and one control group, blind and randomized, in phase three with 120 samples.

Settings and conduct

This study will be carried out in the clinical departments of Besat Hospital in Sanandaj. The method of intervention is to include inhalation of chamomile - lavender essence and listening to music for 20 minutes during the rest of the staff in three intervention groups. There is no action in the control group. The intervention will be carried out by the first researcher collaborator. The second researcher will collect questionnaires. In this research, The second researcher and the statistical advisor will be blind to the intervention.

Participants/Inclusion and exclusion criteria

Entry criteria: Voluntary participationtudy, No thyroid dysfunction or mental illness, No anti-anxiety drugs Exit criteria: Having allergies to the essance

Intervention groups

The first intervention group included inhalation of the essence of chamomile- lavender. The second intervention group included listens to the music. The third intervention group combined of inhalation of the essence of chamomile - lavender and listens to the music. In the control group, intervention will not be performed.

Main outcome variables

Fatigue; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041106N1**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **retrospective**

Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date

2018-11-30, 1397/09/09

Registrant information

Name

somayeh zamanifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3378 0079

Email address

zamanifar.s@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-26, 1397/07/04

Expected recruitment end date

2018-11-25, 1397/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of music therapy and aromatherapy of

chamomile-lavender on fatigue and anxiety of nurses working in Besat hospital of Sanandaj in 2018

Public title
The effect of music therapy and aromatherapy of chamomile-lavender on fatigue and anxiety

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Voluntary participation in the study Not being in critical condition No thyroid dysfunction or mental illness such as anxiety Not taking any anxiety and analgesics during the study Have at least 6 months of work experience Not having any history of life events and crises in the last 6 months Have a sense of smell Absence of respiratory diseases, asthma and allergic diseases Non pregnancy, breastfeeding Having a working shift No vacation or sick leave during the study Earn at least a score of 8 from the Beck Anxiety Inventory No perfume in the day of study Interest in listening to music

Exclusion criteria:
Having allergies

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, Stratified randomization will be used. Randomization is done particularly in each hospital ward as a Stratify. Considering having ten clinical wards as ten stratifies and a sample size of 120 samples, 12samples were considered from each Stratify. Randomized allocation of samples to groups in each Stratify will be applied based on lottery cards numbered 1 to 4 (for each group of three cards) without replacement of cards.assigned to each group and 12 will be allocated to four groups based on each other. From these quotas assigned in each category based on the draw of random numbers, One to four (number of groups) without substitution in each section will be assigned randomly to the groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The method of blindness in this study is that the second-degree fellow will not be aware of the type of intervention. The first research partner in each of the three intervention groups will take the necessary interventions. The coding of the questionnaire and information registration forms based on the number assigned to the random sampling will be the responsibility of the main investigator. The second collaborator of the research after the end of the interventions, without considering and informing the groups, will refer to the samples for collecting the data based on this code and will be blind to the type of intervention. Also, all questionnaires will be given to the statistical consultant by the original researcher based on the coding, so the statistician will also be blind to the type of intervention.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kurdistan University of Medical Sciences

Street address
Kurdistan University of Medical Sciences, after Qods Hospital

City
Sanandaj

Province
Kurdistan

Postal code
66177-13446

Approval date
2018-09-04, 1397/06/13

Ethics committee reference number
IR.MUK.REC.1397.102

Health conditions studied

1

Description of health condition studied
Fatigue and anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fatigue severity

Timepoint
Before the intervention and after three shifts

Method of measurement
Krupp Fatigue Severity Scale et al

2

Description
Anxiety
Timepoint
Before the intervention and after three shifts
Method of measurement
Beck anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In the first intervention group, the aroma of chamomile-lavender will be used. The aroma of this research will be used the combination of lavender-chamomile 1.5% by inhalation breathing. Chamomile and lavender plants will be provided by Zardvand Pharmaceutical Company. Then, Shahid Beheshti Pharmaceutical Faculty will then extract it by distillation with water, after which it will be diluted 5% in the sesame oil base. This essential oil is prepared for each sample of three drops on a pre-prepared non-absorbent pad and will be inhaled at a distance of 20 cm from the nose for 20 minutes at rest.
Category
Prevention

2

Description
Intervention group 2: In the second intervention group, music therapy will be performed. In the music band, the intervention will be such that pre-designated music (traditional, pop, classical) will be selected as desired. Headphones will be used to play music. Music will be played for 20 minutes each time. This intervention will be performed over three consecutive shifts.
Category
Prevention

3

Description
Intervention Group 3: For nurses in this group simultaneously inhale the scent of Lavender Chamomile and listen to the desired music. Three drops of lavender chamomile will be prepared on one and a half percent on a pre-prepared, Non-absorbent pad. It will be inhaled at 20 cm from the nose for 20 minutes. From pre-set music (traditional, pop, classical), samples will be played back for 20 minutes. This intervention will be performed over three consecutive shifts
Category
Prevention

4

Description
Control group: Due to the fact that the samples are not sick and nursing, They do not receive any special treatment. Therefore, There is no specific action in the control group, but ethically, After the end of the study, The interventions will be done for the control group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Somayeh Zamanifar
Street address
Besat Hospital, Keshavarz Street, Sanandaj
City
Sanandaj
Province
Kurdistan
Postal code
6619616776
Phone
+98 87 3328 5910
Fax
+98 87 3366 3905
Email
zamanifarnursing@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Farzin Rezaee
Street address
Vice Chancellor for research and technology of Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj
City
Sanandaj
Province
Kurdistan
Postal code
13446-66177
Phone
+98 87 3182 7464
Fax
+98 87 3336 6095
Email
zamanifarnursing@gmail.com
Grant name
Vice Chancellor for research and technology of Kurdistan

University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Somayeh Zamanifar

Position

Nurse/MS.C

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Besat Hospital, Keshavarz Street , sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

6619616776

Phone

+98 878733285910

Email

zamanifarnursing@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Jamal Siedi

Position

Ph.D, Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

13446-66177

Phone

+98 87 3182 7464

Fax

+98 87 3336 6095

Email

jamal.seidi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Jamal Seidi

Position

Ph.D/Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

13446-66177

Phone

+98 87 3182 7464

Fax

+98 87 3336 6095

Email

jamal.seidi@yahoo.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