

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 participation study, No thyroid dysfunction or mental illness, No anti-anxiety drugs Exit criteria: Having allergies to the essence

##### 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

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##### 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, 12 samples 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

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## **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**

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#### **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

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## Person responsible for updating data

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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**  
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