

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Benson relaxation on sleep quality and quality of work life of operating room staff

#### Protocol summary

##### Study aim

Specific Objectives: 1. Determination and comparison of mean sleep quality score and quality of work life in operating room staff of hospitals affiliated to Shiraz University of Medical Sciences based on demographic characteristics before and after intervention in both groups (control group and intervention group) 2. Determination of relationship between sleep quality score and quality of work life of operating room staff of Shiraz University of Medical Sciences hospitals before and after intervention 3. Determination of difference in sleep quality score of operating room staff of hospitals affiliated to Shiraz University of Medical Sciences based on demographic characteristics before and after intervention in both groups 4. Determination of the difference in quality of work life of operating room personnel of hospitals affiliated to Shiraz University of Medical Sciences based on demographic characteristics before and after intervention in both groups

##### Design

The clinical trial consisted of two control and intervention groups, simple randomized. 180 sample numbers

##### Settings and conduct

operating room in hospital

##### Participants/Inclusion and exclusion criteria

1- Having at least an associate's degree or bachelor's degree in operating room personnel 2- Having a desire to participate in research 3. They have not taken any pain medication in the past month (21, 26). 4. According to the standards of the questionnaires, a Pittsburgh score of less than or equal to 5 and a Walton score of moderate (56-88) and low (24-55) are required (6). Exclusion criteria: During the intervention, each person in both groups (control and intervention) had taken sedative and sedative medication. 2. The daily performance log table is empty

##### Intervention groups

Operating Room Personnel Associate Degree and Master of Operating Room

#### Main outcome variables

Quality of sleep, quality of working life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100919004775N12**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

##### Registration date

2019-10-31, 1398/08/09

##### Registrant information

##### Name

Zinat Mohebbi

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4254

##### Email address

zmohebi@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-22, 1398/06/31

##### Expected recruitment end date

2019-11-21, 1398/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of Benson relaxation on sleep quality and quality of work life of operating room staff

**Public title**  
The effect of Benson relaxation on sleep quality and quality of working life

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Minimum of associate's degree or bachelor's degree in practice room Personnel Willing to participate in research  
Have not used hypnotic drugs in the past month  
**Exclusion criteria:**

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **180**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Specify sample size: Sample size was randomly assigned using NCSS software with 80% power, 5% type I error, and using similar data (24), mean and standard deviation, in control group (32) and intervention group (95%). / 52) 90 persons were assigned to each group. How to choose a sample: First, with a coin and the use of a toss, we specify that the numbers 1 to 90 (the first 90) fall into the intervention group and the numbers 91 to 180 (the second 90) into the control group. The number of cards will be numbered from one to 180 and will be distributed among those who meet the criteria for admission to the study. Based on the number of operating room staff in each hospital, we determine in advance how many numbers are to be assigned to each hospital and then enter the intervention group as the numbers that emerge. To compensate for the loss, the number of intervention and control groups will be greater than 90 each.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Factorial

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Eram. khabgah Eram6

##### City

Shiraz

##### Province

Fars

##### Postal code

7194685791

##### Approval date

2019-08-28, 1398/06/06

##### Ethics committee reference number

1398.657

## Health conditions studied

### 1

#### Description of health condition studied

Work life quality

##### ICD-10 code

##### ICD-10 code description

## Primary outcomes

### 1

#### Description

Sleep Quality: A state of sleep that can be defined as its effect on the amount of fatigue during waking up during the day or the feeling of being happy and well after waking up and the number of waking up at night. Sleep quality, sedentary sleep, feeling of well-being and well-being after waking up in operating room personnel during the intervention were measured before and after the intervention using the Pittsburgh Sleep Quality Assessment Tool. In this study, operating room personnel will be recruited based on the scale of the questionnaire if they score less than or equal to 5.

#### Timepoint

Before the intervention and 2 months after the intervention

#### Method of measurement

Pittsburgh Sleep Quality Questionnaire

### 2

#### Description

Quality of Work Life: How much one feels and understands the physical and psychological state of their workplace. In this study, quality of work life is a score obtained by operating room personnel. What improves it is to increase hospital productivity. Before and after the intervention, Walton measured the quality of work life. In this study, operating room staff will be recruited based

on the scale of the questionnaire if they score moderate (56-88) and low (24-55) on the quality of working life.

**Timepoint**

before the intervention and 2 months after the invention

**Method of measurement**

Waltons questionnair

**Secondary outcomes****1****Description**

Benson Relaxation Intervention: Relaxation is a state in which one's stress is at a low level and emotional levels, especially anxiety, fear and anger, are reduced. The process used to create this condition is called relaxation or relaxation. In a specific sense, the return of a contracted muscle back to its original state of relaxation is the purpose of this study of relaxation, a method introduced by Herbert Benson in 1970 and performed in four stages: 1. Providing a relaxed environment. Being in a comfortable state of mind3- Creating a mental focus 4- Creating a passive state of sampling The subjects are asked to do it twice a day for 20 minutes each time for 4 weeks.

**Timepoint**

During the intervention for 2 months

**Method of measurement**

Pittsburgh Sleep Quality Questionnaire and Walton Quality of Work Life Questionnaire

**Intervention groups****1****Description**

Intervention group: Intervention group: Operating room personnel with bachelor's, associate's and master's degree, obtained a score of less than or equal to 5 by the Pittsburgh Questionnaire and a mean score (56-88) and a low score (24-55) by the Quality of Work Questionnaire. They practice Benson relaxation for 2 months. After that, they receive the questionnaires again and calculate their effects by calculating their scores.

**Category**

Lifestyle

**2****Description**

Control group: Operating room personnel with a bachelor's, associate's, and master's degree, earned a score of less than or equal to 5 using the Pittsburgh Questionnaire and a moderate (56-88) and a low (24-55) quality of work life questionnaire. They do not practice Benson relaxation for 2 months and during this time they do not take any traditional or traditional sedatives.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Namazi Hhospital, Rajaii, Chamran, Khalili, Shahid Faghihi

**Full name of responsible person**

Maryam Ghanavati

**Street address**

Eram. khabgah eram6.room26

**City**

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**Province**

Fars

**Postal code**

7194685791

**Phone**

+98 71 3628 2700

**Email**

technologist96@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

janghorban zade

**Street address**

zand

**City**

Shiraz

**Province**

Fars

**Postal code**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Shiraz University 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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Maryam Ghanavati  
**Position**  
msc student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
surgery  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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technologist96@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

### Full name of responsible person

maryam ghanavati

### Position

msc student

### Latest degree

Master

### Other areas of specialty/work

surgery

### Street address

eram

### City

shiraz

### Province

Fars

### Postal code

7194685791

### Phone

+98 71 3628 2700

### Email

technologist96@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Information on the impact of the secondary outcome on the primary outcome is published.

### When the data will become available and for how long

One year after the results were published

### To whom data/document is available

Research participants and hospitals

### Under which criteria data/document could be used

To the participants if they remain in the research until the last stage

### From where data/document is obtainable

Phone 09386688127 or email Maryam Ghavnati. technologist96@gmail.com

### What processes are involved for a request to access data/document

Requesting the above email will request the results of the research.

### Comments