Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 numbersقاتا

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

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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

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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

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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 updating data

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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