

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of Benson's Relaxation on QoL in operating room personnel of hospitals affiliated to Shiraz University of Medical Sciences.

#### Protocol summary

##### Study aim

1. Determination and comparison of QoL score mean in operating room personnel of hospitals affiliated to Shiraz University of Medical Sciences based on demographic characteristics before, 4 and 8 weeks after intervention in both groups (control and intervention) 2. Determination of difference in QoL score in operating room personnel of hospitals affiliated to Shiraz University of Medical Sciences based on demographic characteristics before, 4 and 8 weeks after intervention between both groups (control and intervention)

##### Design

A clinical trial is done with control and intervention groups, single blinding, simple randomization, on 180 operating room personnel.

##### Settings and conduct

Benson's relaxation intervention: In this study relaxation means a method introduced by Herbert Benson in 1970 and performed in four stages. The samples are asked to do it twice a day for 20 minutes each time, for 8 weeks. The intervention took place at Namazi, Rajaii, Chamran, Khalili and Faghihi Hospitals.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having at least associate's, bachelor's or master's degree of operating room 2- Willing to participate in research 3- Gaining a QOL score less than 50, according to the SF-36 questionnaire  
Exclusion criteria: Have not completed the Benson's relaxation schedule form

##### Intervention groups

Intervention group: Benson's Relaxation is taught to the participants of this group. People should practice Benson's relaxation twice a day at 6-hour intervals.  
Control group: The participants of this group are not given relaxation.

##### Main outcome variables

QoL of operating room personnel according to SF-36 questionnaire that is measured before, 4 and 8 weeks after intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211002052650N1**

Registration date: **2022-10-26, 1401/08/04**

Registration timing: **prospective**

Last update: **2022-10-26, 1401/08/04**

Update count: **0**

##### Registration date

2022-10-26, 1401/08/04

##### Registrant information

##### Name

Maryam Ghanavati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5234 2947

##### Email address

technologist96@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-12, 1401/08/21

##### Expected recruitment end date

2023-02-09, 1401/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Benson's Relaxation on QoL in operating room personnel of hospitals affiliated to Shiraz University of Medical Sciences.

**Public title**

The effect of Benson's Relaxation on QoL

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having at least Associate's, Bachelor's or Master's degree Willing to participate in research Gaining a QoL score less than 50, according to the SF-36 questionnaire

**Exclusion criteria:**

Not having completed the Benson's relaxation Schedule form

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Specify sample size: Sample size was simple randomly assigned using NCSS software with 80% power, 5% type I error, and using previous similar data, mean and standard deviation, in control and intervention groups, 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 1 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 and control groups as the numbers that emerge. in the same order as mentioned. To compensate for the drop, the number of intervention and control groups will be more than 90 each.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

outcome assessor blinding

**Placebo**

Not used

**Assignment**

Parallel

**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**

Zand Street, Namazi Hospital, Nursing and Midwifery College.

**City**

Shiraz

**Province**

Fars

**Postal code**

71936-13119

**Approval date**

2020-02-16, 1398/11/27

**Ethics committee reference number**

IR.SUMS.REC.1398.1331

**Health conditions studied****1****Description of health condition studied**

Quality of life (QoL)

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

SF-36 QoL of Operating Room Personnel

**Timepoint**

Before, 4 and 8 weeks after intervention

**Method of measurement**

SF-36 QoL

**Secondary outcomes**

empty

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

Intervention Group: Benson's Relaxation is taught to Operating Room Personnel that carried out twice a day, each time for 20 minutes, at 6-hours intervals. Quality of life is measured before, 4 and 8 weeks after intervention.

**Category**

Lifestyle

**2****Description**

Control Group: The Operating Room Personnel of this

group are not given teaching. Quality of life is measured before, 4 and 8 weeks after intervention.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

All of the Educational Hospitals of Shiraz.

**Full name of responsible person**

Zinat Mohebbi

**Street address**

Zand Street, Namazi Hospital, Nursing and Midwifery College.

**City**

Shiraz

**Province**

Fars

**Postal code**

71936-13119

**Phone**

+98 71 3647 4256

**Fax**

+98 71 3647 4252

**Email**

mohebbi04@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Roxana Ganghorban

**Street address**

Zand Street, Namazi Hospital, Nursing and Midwifery College.

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71936-13119

**Phone**

+98 71 3647 4256

**Fax**

+98 71 3647 4252

**Email**

researchnu@sums.ac.ir

**Grant name**

98-01-42-20364

**Grant code / Reference number**

20364

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Zinat Mohebbi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Contact**

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## Person responsible for updating data

### Contact

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Shiraz University of Medical Sciences

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

We do not have data yet.

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

One year after the results were published.

**To whom data/document is available**

Researcher, 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 00989177137573 or email Zinat Mohebbi:  
mohebbi04@yahoo.com.

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

Email to Zinat Mohebbi and want the result of the research.

**Comments**