

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### The effect of Benson relaxation on quality of life in adolescents undergoing bone marrow transplantation

#### Protocol summary

##### Study aim

Determining the effect of Benson relaxation on quality of life in adolescents undergoing bone marrow transplantation

##### Design

In this randomized clinical trial, patients will be randomly assigned to two groups of 25 people.

##### Settings and conduct

This study will be performed in Tehran Pediatric Medical Center. 50 patients are randomly divided into two groups of intervention and control. Outcomes are assessed immediately after the intervention and one month after. Blinding is not done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 12-18 years, Having the consent to participate in the study, No known psychiatric disorders, dementia and mental retardation. Exclusion criteria: Use of other Complementary therapies

##### Intervention groups

In the intervention group, Benson relaxation technique will be performed for 20 minutes during two months (daily, twice daily). The control group will be performed no intervention for two months and will receive routine care such as medication.

##### Main outcome variables

Quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111210008348N49**  
Registration date: **2020-08-28, 1399/06/07**  
Registration timing: **prospective**

Last update: **2020-08-28, 1399/06/07**

Update count: **0**

##### Registration date

2020-08-28, 1399/06/07

##### Registrant information

###### Name

Neda Mirbagher

###### Name of organization / entity

Kashan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1555 0021

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-10, 1399/06/20

##### Expected recruitment end date

2020-12-20, 1399/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Benson relaxation on quality of life in adolescents undergoing bone marrow transplantation

##### Public title

The effect of Benson relaxation on quality of life

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age 12-18 years Having the consent to participate in the study. No known psychiatric disorders, dementia and

mental retardation

**Exclusion criteria:**

Use of other Complementary therapies

**Age**

From **12 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation in two groups of intervention and control will be simple randomization. Randomization is carried out by creating a random sequence of numbers using a randomizer tool (<https://www.randomizer.org>).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Approval date**

2020-04-18, 1399/01/30

**Ethics committee reference number**

IR.KAUMS.NUHEPM.REC.1399.007

## Health conditions studied

1

**Description of health condition studied**

Benson relaxation

**ICD-10 code**

Z50

**ICD-10 code description**

Care involving use of rehabilitation procedures

## Primary outcomes

1

**Description**

Quality of Life

**Timepoint**

Before, immediately after the end of the study and one month later

**Method of measurement**

Questionnaire to assess the quality of life of cancer patients at the European Cancer Research and Treatment Center

## Secondary outcomes

empty

## Intervention groups

1

**Description**

Intervention group: Intervention group: In addition to routine care (physiotherapy, light exercise, medication), the Benson relaxation technique will be performed during two months (every day, twice a day) for 20 minutes. The Benson's relaxation technique includes the following steps: Being comfortable, closing eyes, relaxing all the muscles of the body, breathing slowly.

**Category**

Prevention

2

**Description**

Control group: Routine care including joint physiotherapy, light exercise, medication will be performed for patients by health personnel.

**Category**

N/A

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Tehran Children's Medical Center

**Full name of responsible person**

Neda Mirbagher

**Street address**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Hamid Reza Banafsheh  
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Vice Chancellor of Research & Technology, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran  
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banafshe\_h@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Kashan 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**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Neda Mirbagher  
**Position**  
Assistant Professor  
**Latest degree**

Ph.D.  
**Other areas of specialty/work**  
Nursery  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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Fatemeh Fatholahi  
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Master's degree student in nursing  
**Latest degree**  
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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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable