

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effect of progressive muscle relaxation training on anxiety, depression and quality of life in cancer patients under chemotherapy in Tabriz Hematology & Oncology Center-1388

#### Protocol summary

##### Summary

The aim of this study is to determine Anxiety, Depression and Quality of life dimensions of cancer patients under chemotherapy and the effect of progressive muscle relaxation training to promote health and improve their Quality of life. Sixty cancer patients under chemotherapy will be selected randomly and will be divided into two groups of intervention and control. To measure Anxiety & Depression, and Quality of life dimensions, HADS and EORTC QLQ-C30 questionnaires will be completed, respectively. Patients will be trained for progressive muscle relaxation in 3-6 case groups, for doing the practical self-help in the hospital and after discharge, 2-3 times a day. One and three months after intervention, questionnaires will be completed again by both groups, and the results will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138804172103N3**

Registration date: **2010-02-19, 1388/11/30**

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

Last update:

Update count: **0**

##### Registration date

2010-02-19, 1388/11/30

##### Registrant information

###### Name

Iraj Asvadi Kermani

###### Name of organization / entity

Hematology and Oncology Research Center- Tabriz university of medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1334 3844

###### Email address

asvadikermani@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hematology and oncology research center, Tabriz University of Medical Sciences

##### Expected recruitment start date

2009-05-22, 1388/03/01

##### Expected recruitment end date

2010-05-22, 1389/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of progressive muscle relaxation training on anxiety, depression and quality of life in cancer patients under chemotherapy in Tabriz Hematology & Oncology Center-1388

##### Public title

The effect of progressive muscle relaxation training on anxiety, depression and quality of life in cancer patients under chemotherapy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Agreed to participate, Ability to read and write Farsi, Age range of 15-65 years, Receiving minimum 2 cycles of chemotherapy, Having mental health Inclusion Criteria: receiving pharmacological and

non pharmacological interventions for Anxiety and Depression, history of chronic and high risk disease as diabetes, receiving both chemotherapy and radiotherapy, Patients with subscale scores 0-7 (HADS-A), 0-4 (HADS-D), or 0-10 (HADS-T)

#### Age

From **15 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### 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

Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, University Ave.

##### City

Tabriz

##### Postal code

#### Approval date

2009-01-06, 1387/10/17

#### Ethics committee reference number

5/4/2517

## Health conditions studied

### 1

#### Description of health condition studied

Training

#### ICD-10 code

Z50.8

#### ICD-10 code description

Training in activities of daily living

### 2

#### Description of health condition studied

Training

#### ICD-10 code

Z50

#### ICD-10 code description

Care involving use of rehabilitation procedure

## Primary outcomes

### 1

#### Description

Level of anxiety and depression

#### Timepoint

1 and 3 Month after intervention

#### Method of measurement

HADS questionnaire

### 2

#### Description

Dimensions of quality of life

#### Timepoint

1 and 3 Month after intervention

#### Method of measurement

EORTC QLQ-C30 questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Patients in 3-6 case groups will be trained to progressive muscle relaxation technique. We advise doing these techniques as self-help in the hospital and after discharge home at least 2 or 3 times a day, especially before night sleep. One and three months after the intervention, HADS and EORTC QLQ-C30 questionnaires again will complete by control and case groups. Progressive relaxation technique: this technique involves alternately tensing and relaxing the muscles and technique session takes approximately 30 minutes. A person may start by sitting or lying down in a comfortable position with the eyes closed; the muscles are tensed (10 seconds) and relaxed (20 seconds) in sequence as per the following progressive pattern: the tension of the lower arms, upper arms, lower legs, upper legs, stomach, chest, shoulders, neck, mouth, eyes, lower forehead, upper forehead. After doing each of these muscle groups, the patient should feel collectively relaxed and warm.

#### Category

*empty*

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Hematology and Oncology Center, Tabriz, Iran

**Full name of responsible person**

Dr. Iraj Asvadi Kermani

**Street address**

Shahid Ghazi Tabatabaei Hospital, Hematology and Oncology research center, Tabriz University of Medical Sciences

**City**

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**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hematology and oncology research center, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Iraj Asvadi Kermani

**Street address**

Shahid Ghazi Tabatabaei Hospital, Hematology and oncology research center, Tabriz University of Medical Sciences

**City**

Tabriz

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

Yes

**Title of funding source**

Hematology and oncology research center, Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Iraj Asvadi Kermani

**Position**

Hematologist and Oncologist- Professor

**Other areas of specialty/work****Street address**

Shahid Ghazi Tabatabaei Hospital, Hematology and

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Sepideh Herizchi Ghadim

**Position**

Psychiatrist

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Mehri Golchin

**Position**

MSN in nursing

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## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*