Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of progressive muscle relaxation technique on fatigue, depression, and quality of life in patients with hypothyroidism

Protocol summary

Study aim
Determining the effect of progressive muscle relaxation technique on fatigue, depression, and quality of life in patients with hypothyroidism.

Design
A randomized clinical trial with two intervention and control groups, two-way Gore on 64 patients, using random numbers generated by software for randomization.

Settings and conduct
This project is being carried out in Khomein City Hospital. After selecting patients who met the study entry criteria and gave informed consent to the study, they were asked to complete demographic information questionnaires, Piper fatigue, BDI-2 depression, and the Thyroid Disease Patients Quality of Life Questionnaire (ThyPRO39IR). After teaching the intervention to the patients and explaining how to implement it, the questionnaires were completed again at the end of the study.

Participants/Inclusion and exclusion criteria
Entry requirements: No communication problems, no physical problems, full proficiency in Persian, informed consent, age over 18 years, not pregnant for women, confirmation of clinical hypothyroidism by a specialist physician, no cognitive problems, no previous experience using this technique, having a personal mobile phone or the presence of someone at home who has a mobile phone, no drug addiction؛ Exclusion requirements: Unwillingness to continue participating in the study, occurrence of any disabling physical disorder, pregnancy, any problems for the patient during the study, occurrence of a psychological crisis such as mourning or divorce.

Intervention groups
To examine the PMRT technique, patients in the intervention group are asked to perform PMRT exercises at home for 4 weeks, twice a day for 20 minutes each time, after learning the technique. During this period, patients in the control group receive only routine care.

Main outcome variables
Fatigue; Depression; Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250605066079N1**
Registration date: **2025-07-04, 1404/04/13**
Registration timing: **prospective**

Last update: **2025-07-04, 1404/04/13**
Update count: **0**

Registration date
2025-07-04, 1404/04/13

Registrant information

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Sara Mohammadi Farsani

Name of organization / entity
The University of Khomein

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-16, 1404/04/25

Expected recruitment end date
2026-04-14, 1405/01/25

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of progressive muscle relaxation technique on fatigue, depression, and quality of life in patients with hypothyroidism

Public title
Investigating the effect of progressive muscle relaxation technique on fatigue, depression, and quality of life in patients with hypothyroidism
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
No communication problems Not having a physical problem that prevents you from exercising. Complete fluency in Persian No medical record indicating neurological or mental problems and no use of medications related to this problem Voluntary consent to participate in the study Over 18 years old Not being pregnant for women Confirmation of clinical hypothyroidism by a specialist physician Absence of cognitive problems or impairment No previous experience using this technique Having a personal cell phone or having someone in the house who has a cell phone No drug addiction
Exclusion criteria:
Unwillingness to continue participating in the study for any reason The occurrence of any disabling physical disorder during the study that prevents movement Pregnancy during the study period ایجاد هر گونه مشکل در طول مطالعه برای بیمار The occurrence of a psychological crisis such as bereavement or divorce during the intervention period
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two groups: intervention and control, using simple random numbers generated by software.
Blinding (investigator's opinion)
Double blinded
Blinding description
In fact, this study is double-blind, so that the physician, members of both the intervention and control groups, the researcher who is responsible for administering the questionnaires at the end, and the analyst are blinded to the members of the groups.
Placebo
Not used
Assignment
Other
Other design features
In this study, the control group receives only routine treatments.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khomein Faculty of Medical Sciences
Street address
Khomein, Qods Blvd., Faculty of Medical Sciences
City
Khomein
Province
Markazi
Postal code
3881743364
Approval date
2025-06-09, 1404/03/19
Ethics committee reference number
IR.KHOMEIN.REC.1404.009

Health conditions studied

1

Description of health condition studied
Hypothyroid
ICD-10 code
ICD-10 code description
Patients with clinically confirmed hypothyroidism

Primary outcomes

1

Description
Fatigue
Timepoint
At the beginning of the study and at the end of the study (4 weeks)
Method of measurement
Piper Fatigue Scale

2

Description
depression
Timepoint
At the beginning of the study and at the end of the study (4 weeks)
Method of measurement
BDI-2 depression questionnaire

3

Description
quality of life
Timepoint
At the beginning of the study and at the end of the study (4 weeks)
Method of measurement
Quality of Life Questionnaire for Patients with Hypothyroidism (ThyPRO39IR).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Patients in the intervention group will be taught the PMRT technique by the researcher in a separate room for 40 minutes. Then, they will be asked to perform this technique twice a day (morning and evening) for 20 minutes each time for 4 weeks based on the educational video sent to them. Patients will be instructed to take levothyroxine tablets in the morning on an empty stomach and not to eat anything for one hour after taking it that may interfere with the absorption of the drug and aggravate the symptoms of hypothyroidism. Patients will be instructed to avoid taking dietary supplements containing iodine and selenium, which affect the activity of the thyroid gland, during the intervention period without consulting a doctor and informing the researchers. Patients will be asked to avoid changing their diet or taking herbal medicines without consulting a doctor and informing the researchers during the intervention period, and they will be instructed to keep their diet constant during this period. In addition, these patients are monitored by telephone every week to ensure that the instructions and training given are carried out correctly. At the end of 4 weeks, the questionnaires are completed by making a telephone call to the members of the intervention group by researcher number 2, who is outside the study group and blinded to the members of both groups, and the information obtained is compared.
Category
Rehabilitation

2

Description
Control group: Patients in this group are not given any information about PMRT and receive their routine treatments during the study period. They are only asked to complete the demographic information questionnaire, the Pepper Fatigue Questionnaire, and the ThyPRO-39 Quality of Life Questionnaire at the beginning and end of this period. These patients are monitored every week via telephone call and information about their health status is obtained.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatima Al-Zahra Khomein Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khomein Faculty of Medical Sciencesl
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Abbas Farahani
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khomein Faculty of Medical Sciencesl

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
Khomein Faculty of Medical Sciences
Full name of responsible person
Sara Mohammadi Farsani
Position
Student
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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available