

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the effect of jakobsons muscle relaxation technique on psychological well-being and resilience in patients with type 2 diabetes

Protocol summary

Study aim

Determining the effect of Jacobson muscle relaxation technique on psychological well-being and resilience of patients with type 2 disease

Design

Randomized clinical trial with two control and intervention groups on 48 patients with type 2 diabetes. The permutation block method will be used for randomization

Settings and conduct

Patients with type 2 diabetes who refer to the diabetes clinic of Hakim Hospital in Neishabour are selected by convenience sampling method and assigned to the control and intervention groups by permutation block method.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes who are at least 6 months old

Intervention groups

In the muscle relaxation intervention group, the relaxation method is taught to the patients by the researcher in such a way that the patients are comfortable lying down or sitting, do not put their legs and arms on top of each other, and minimize body movements. Breathe slowly and orderly during the session. Tighten each muscle group for 5 to 7 seconds and then loosen and relax for 30 to 40 seconds at the researcher's mark. The tension should be such that there is no muscle pain. Usually relax. Each muscle group is performed twice. We teach patients to become more alert as we get closer to one another. When we reach one, open their eyes. After teaching this intervention, it is performed once by the patient in the presence of the researcher, and the scale of its accuracy is the expression of the feeling of relaxation of the muscles after the intervention by the patients. Then an audiotape is provided for people to relax every day at home and in a quiet environment. The researcher will also monitor the intervention by phone or text message. In the control

group, no intervention is performed except for the usual care of the center.

Main outcome variables

Psychological well-being, resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220110053682N1**

Registration date: **2022-02-21, 1400/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-21, 1400/12/02**

Update count: **0**

Registration date

2022-02-21, 1400/12/02

Registrant information

Name

Zahra Abolfazli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4223 8456

Email address

abolfazliz99@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of jakobsons muscle relaxation technique on psychological well-being and resilience in patients with type 2 diabetes

Public title

Evaluation the Effect of Jakobsons Muscle Relaxation Technique on Psychological Well-being and Resilience in Patients With Type 2 Diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Have a minimum reading and writing literacy Acceptable hearing and speech ability Age range 25 to 65 years No history of receiving relaxation training Have at least 6 months of type 2 diabetes No smoking and alcohol Possibility to use the training file Having a mobile phone to make calls Psychological well-being score equal to or less than 63 Resilience score equal to or less than 50

Exclusion criteria:

Having physical and mental disabilities Suffering from diseases that require medical care Reluctance to participate in research

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were placed in two groups A and B by permutation block method using the site <https://www.Randomization.com> and were sealed in opaque envelopes in order to hide the allocated samples, which was sealed by the supervisor prepared are provided to the researcher

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 Sabzevar University of Medical Sciences

Street address

No. 31, Towhid shahr Ave, Shohada Gomnam Blvd, campus of Sabzevar University of Medical Sciences, sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112_31 صندوق

Approval date

2022-01-03, 1400/10/13

Ethics committee reference number

IR.MEDSAB.REC.1400.137

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

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Resilience

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Connor & Davidson Resilience Questionnaire

Secondary outcomes**1****Description**

Psychological well-being

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Ryff's Psychological Well being questionnaire

Intervention groups

1

Description

Intervention group: Muscle relaxation is maintained by contracting each muscle group for 5 to 7 seconds and then 30 to 40 seconds, and this is done twice for each group. This operation is performed daily for 2 months. The correct criterion for justice relaxation is feeling relaxed in different muscle groups.

Category

Other

2

Description

Control group: Without any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khayyam Clinic, Hakim Hospital, Neishabour

Full name of responsible person

Zahra Abolfazli

Street address

At the beginning of Baghroud Road, Hakim Research and Medical Training Center

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Neyshabour

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9318684854

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HakimHospital@nums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Qarat

Street address

No. 31, Towhidshahr Ave, Shohada Gomnam Blvd,
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Email

vcResearch@medsab.ac.ir

Web page address

<http://medsab.ac.ir/index.aspx?pageid=125>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Abolfazli

Position

Master Student Of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Ali Asghar Jesmi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some of the research sample data will be shared after being unidentified.

When the data will become available and for how long

After collecting and analyzing the data, the results will be published as an article.

To whom data/document is available

The results will be published for all researchers in the class.

Under which criteria data/document could be used

The results of this study can be used by all people in the field of treatment and care of patients with type 2 diabetes.

From where data/document is obtainable

Applicants can refer to Ms. Zahra Abolfazli at Sabzevar University of Medical Sciences, School of Nursing and Midwifery, Student Research Committee, to obtain research documents.

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

Applicants can access the documentation to obtain the documentation after submitting an application to the Student Research Committee and obtaining the necessary permits.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Abolfazli

Position

Master Student Of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

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