Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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, Campus of Sabzevar University of Medical Sciences, Sabzevar

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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

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Full name of responsible person
Ali Asghar Jesmi

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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