

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the effect of life skills training on reducing domestic violence and adherence to treatment in women with type 2 diabetes

Protocol summary

Study aim

The effect of life skills training based on self-efficacy theory on reducing domestic violence and adherence to treatment in women with type 2 diabetes in Bushehr city.

Design

A randomized controlled clinical trial on 100 patients in a randomized block

Settings and conduct

Workshop method will be used to provide life skills training based on self-efficacy theory. The number of sessions is eight 2-hour sessions twice per week for one month. This study will be conducted in diabetes clinic, comprehensive health centers and selected hospitals of Bushehr city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having consent to enter the study. Women suffering from domestic violence with type 2 diabetes living with their husbands, patients must be over 30 years old and up to 70 years old. Exclusion criteria: Women with neurological, mental disorders and chronic disease by special caring.

Intervention groups

The intervention group participates in 8 2-hour sessions of life skills training based on self-efficacy theory. But the control group does not receive any training.

Main outcome variables

Domestic violence, Treatment Adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090522001930N6**

Registration date: **2022-10-14, 1401/07/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-14, 1401/07/22**

Update count: **0**

Registration date

2022-10-14, 1401/07/22

Registrant information

Name

Hakimeh Vahedparast

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-11, 1401/06/20

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of life skills training on reducing domestic violence and adherence to treatment in women with type 2 diabetes

Public title

The Effect of Life Skills Training Based on Self-Efficacy Theory on Reducing Domestic Violence and Treatment Adherence in Women with Type-2 Diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be married and have a life with a spouse. Suffering from type 2 diabetes diagnosed by a specialist doctor or being treated with medication Subject to domestic violence and has received at least 60 points from the domestic violence questionnaire At least 6 months have passed since contracting the disease Have full listening and speaking ability. At least have the ability to read and write patients must be over 30 years old and up to 70 years old Having consent to enter the study

Exclusion criteria:

She has participated in the life skills class Have relevant education in the field of psychology and counseling Suffering from neuropsychiatric disorders (according to self-report) Suffering from a debilitating physical illness Despite the explanation, the researcher did not understand the questions of the questionnaire Suffering from a chronic disease that requires special care

Age

From **30 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

According to block randomization the research sample will be placed into one of the two groups of intervention and control group. The number of required blocks will be selected randomly. For blocking, 12 blocks of block size of 8 and one block of block size of 4 will be used. In the first step, blocks size 8 are prepared using A (intervention) and B (control group), which will have 70 different modes. Of the blocks, 12 will be randomly selected. By selecting each block size of 8, each one will be placed in one of two groups according to the order of the letters. Each block will receive four chances for each group. Block size 4 will also be provided (6 modes) and one block will be randomly selected. With this block will receive two chances for each groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

Does not have

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Bushehr University of Medical Sciences

Street address

Pardis Site of Bushehr University of Medical of Science, Rishahr St, Bushehr, Iran.

City

Bushehr

Province

Boushehr

Postal code

7518759577

Approval date

2022-08-01, 1401/05/10

Ethics committee reference number

IR.BPUMS.REC.1401.063

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

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitusstable

2**Description of health condition studied**

Non-adherence to treatment

ICD-10 code

Z91. 1

ICD-10 code description

noncompliance with medical treatment and regimen

3**Description of health condition studied**

Domestic violence

ICD-10 code

T74. 1

ICD-10 code description

maltreatment (physical abuse) by spouse

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

Domestic violence

Timepoint

pre- test before the intervention and immediately after the test and 4 weeks(following) after the intervention

Method of measurement

The spousal abuse section of the domestic violence questionnaire of Mohseni Tabrizi et al, including 26 items in 4 fields:(psychological-economical-physical-sexual).scoring is from 26 up to 130.

Secondary outcomes

1

Description

treatment adherence

Timepoint

pre- test before the intervention and immediately after the test and 4 weeks(following) after the intervention

Method of measurement

Summary questionnaire of diabetes self-caring behaviors Tobert et al. including 12 items in five fields(diet, physical activity, self-monitoring of blood sugar, foot care and medication). scoring is from 0 up to 84.

Intervention groups

1

Description

Intervention group:Life skills training based on self-efficacy theory will be done in the intervention group.8 sections of 120 minutes twice per week for one month: The method of Presentation content will be a workshop.

Category

Lifestyle

2

Description

Control group: At the same time, except completing the questionnaires, no intervention will be done in the control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Khaliye Fars hospital

Full name of responsible person

Shahrabano Rezaei

Street address

Taleghani Boulevard, Shohadaye Khaliye Fars hospital

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2

Recruitment center

Name of recruitment center

Bushehr health center

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Diabetes clinic

Full name of responsible person

Shahrabano Rezaei

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Sangi street, Mellat clinic, second floor, diabetes clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Akram Farhadi

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Bushehr, Bahmani, Salman Farsi St., Medical Sciences Campus, 1st floor

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Grant name

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

No

Title of funding source

Bushehr 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

Department of Nursing, Faculty of Nursing and
Midwifery, Bushehr University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hakime Vahdeparast

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for general inquiries

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Person responsible for scientific inquiries

Contact

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Hakime Vahdeparast

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Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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