Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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, Rishehr 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 Khalije Fars hospital
Full name of responsible person
Shahrabano Rezaei
Street address
Taleghani Boulevard, Shohadaye Khalije Fars hospital
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Bushehr
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Boushehr
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Web page address

2

Recruitment center
Name of recruitment center
Bushehr health center
Full name of responsible person
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Salih Abad St., Belolar Valfajr, Bushehr Health Center
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3

Recruitment center
Name of recruitment center
Diabetes clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Hakime Vahedparast
Position
Associate Professor
Latest degree
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Person responsible for updating data

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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

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

Data Dictionary