Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of educational intervention based on family centered empowerment on mental health and health promotion behaviors in elderly women.

Protocol summary

Study aim

Determination and comparison of the effect of family-based empowerment educational intervention on mental health and health promotion behaviors of elderly women in intervention and control group

Design

In this study, 60 eligible elderly women over 60 years of age, who are referred to the elderly health centers of Tabriz, will be randomly divided into intervention and control groups.

Settings and conduct

This study will be conducted in the elderly friendly health centers of Tabriz. sixty eligible people will be selected in a stratified method from 5 centers and will be assigned into two groups of 30 people through blocks 4 and 6 with a 1:1 allocation ratio.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: willingness to participate in the study; Have reading and writing skills; Age 60 and older; Having an active family member to attend training sessions; Female gender for family member; Ability to do routines without the help of others; Not having severe visual and hearing impairment; Not having cognitive and mental illness based on the records of individuals in the SIB system. Exclusion Criteria: Participate in other similar studies; neurological defects (stroke, Parkinson's disease, and paralysis) and known psychological diseases based on patient's remarks and health records; Acute cardiovascular disorders (acute myocardial infarction, heart failure and uncontrolled hypertension) based on patient's statement and health records; Chronic uncontrolled illnesses based on patient records (such as advanced diabetes and malignancies); Restrictive musculoskeletal disorders

Intervention groups

For intervention group, health promotion behaviors based on family-centered model will be taught in 5 sessions of 60 minutes for 5 weeks.The control group will not receive intervention initially

Main outcome variables

Mental health score , Health Promoting Behaviors score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031087N2**
Registration date: **2018-08-03, 1397/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-03, 1397/05/12**
Update count: **0**

Registration date

2018-08-03, 1397/05/12

Registrant information

Name

Shirin Barzanjeh Atri

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

Email address

barzanjehs@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of educational intervention based on family centered empowerment on mental health and health promotion behaviors in elderly women.

Public title
The Impact of Family-Based Education on Mental Health and Health promotion Behaviors of Elderly Women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The desire to participate in the study Have reading and writing skills Age 60 and older Having an active member of the family to attend training sessions Female gender for family member Ability to do routines without the help of others Not having severe visual impairment and hearing loss Not having cognitive and mental illness based on the records of individuals in the SIB system
Exclusion criteria:
Participate in other similar studies Having neurological defects (stroke, Parkinson's disease, and psoriasis) and known psychological diseases based on patient's remarks and health records. Having acute cardiovascular events (acute myocardial infarction, heart failure and uncontrolled hypertension) based on patient's statement and health records Having chronic uncontrolled illnesses based on patient records (such as advanced diabetes and malignancies) Containment of musculoskeletal disorders
Age
From **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A sample of 60 elderly women aged 60 years and over who are eligible for study criteria will be selected by stratified sampling and randomly will be divided into two groups of intervention and control (from each center 12 persons will be selected, 6 women in the intervention group and 6 women in the control group). Allocation Sequence will be generated using Random Allocation Software (RAS) through block sizes 4 and 6 with an allocation ratio of 1:1. Closed identical envelops numbered consecutively will be used to conceal allocations, so no participant, researcher, or statistical analyst will be aware of the type of intervention before assignment to the groups. The allocation sequence will be based on random blocking by the person non-involved in the research. The first person enrolled in the study will receive envelope No. 1, the second one will receive envelope number 2, and this process will continue until the end of sampling.
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 Tabriz University of Medical Sciences
Street address
Central Building No.2, Golgasht Steet, University Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2018-05-15, 1397/02/25
Ethics committee reference number
IR.TBZMED.REC.1397.112

Health conditions studied

1

Description of health condition studied
Elderly Lifestyle
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mental health score in GHQ questionnaire
Timepoint
Before the intervention, 4 and 8 weeks after the intervention
Method of measurement
Mental Health questionnaire (GHQ)

2

Description
Health Promoting Behaviors
Timepoint
Before the intervention, 4 and 8 weeks after the intervention
Method of measurement
Health Promoting Behavior Assessment Questionnaire

Secondary outcomes

1

Description
weight
Timepoint
Before the intervention, 4 and 8 weeks after the intervention
Method of measurement
weight will be assessed using a lever scale with a precision of 100 gr (Seca, Germany)

2

Description
Body mass index(BMI)
Timepoint
Before the intervention, 4 and 8 weeks after the intervention
Method of measurement
using a formula

3

Description
waist
Timepoint
Before the intervention, 4 and 8 weeks after the intervention
Method of measurement
with a tape measure accurate to 1 mm (Laica, Italy)

4

Description
hip circumference
Timepoint
Before the intervention, 4 and 8 weeks after the intervention
Method of measurement
with a tape measure accurate to 1 mm (Laica, Italy)

5

Description
waist to hip circumference
Timepoint
Before the intervention, 4 and 8 weeks after the intervention
Method of measurement
using a formula.

Intervention groups

1

Description
In the intervention group, health promotion behaviors based on the family-centered empowerment model in 5 sessions of 60 minutes for 5 weeks will be taught using lecture and teaching including a researcher-developed educational booklet.
Category
Lifestyle

2

Description
Control group: The control group will not initially receive intervention but after completing the training program, follow-up and completion of the questionnaires, the training will be provided in the form of a meeting with the booklet.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Monempour Health Center
Full name of responsible person
Dr, Ali Agahi
Street address
Zaferanie market, Zaferanieh.
City
Tabriz
Province
East Azarbaijan
Postal code
5166754965
Phone
+98 41 3331 8281
Email
mohammadi188nasrin@gmail.com

2

Recruitment center
Name of recruitment center
Shaheed Babayi Health Center
Full name of responsible person
Dr. Yusef Paknezhad
Street address
Babaei Street 5, shahid Abbas Duran Street,
City
Tabriz
Province
East Azarbaijan
Postal code
5166754985
Phone

+98 41 3385 6478

Email

mohammadi188nasrin@gmail.com

3

Recruitment center

Name of recruitment center

Shahid Bakery Health Center

Full name of responsible person

Dr. Parvin Delpasand

Street address

Opposite Imami Garden, between Qatran and Lalezar square, Pasteur Street

City

Tabriz

Province

East Azarbaijan

Postal code

5173754985

Phone

+98 41 3477 9919

Email

mohammadi188nasrin@gmail.com

4

Recruitment center

Name of recruitment center

Malek Afzali Health Center

Full name of responsible person

Dr. Kazem Golchin

Street address

Opposite of Barenj cemetery, Bareng

City

Tabriz

Province

East Azarbaijan

Postal code

5158854985

Phone

+98 41 3669 4010

Email

mohammadi188nasrin@gmail.com

5

Recruitment center

Name of recruitment center

Dr Mobayen Health Center

Full name of responsible person

Dr. Ramin Mesri

Street address

Between intersection of Shariati and Taleghani, New Pasteur Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138754985

Phone

+98 41 3555 3012

Email

mohammadi188nasrin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Jouyban Abolqasem

Street address

Research Vice Chancellor, third floor, central building number 2, Tabriz University of Medical Sciences, Golgasht street, Azadi Avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3351 1443

Email

ajouyban@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammadi Someae Nasrin

Position

MSc Student Community Health Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, South Shariati Street

City

Tabriz

Province
East Azarbaijan
Postal code
5173863111
Phone
+98 41 3440 9526
Fax
+98 41 3479 6969
Email
mohammadi188nasrin@gmail.com
Web page address
https://nursing.tbzmed.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Shirin Barzanjrh Atri
Position
Instructor, MSc
Latest degree
Master
Other areas of specialty/work
Health Promotion
Street address
School of Nursing and Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5694168451
Phone
+98 41 3475 1706
Fax
+98 41 3479 6969
Email
barzanjehs@tbzmed.ac.ir
Web page address
https://nursing.tbzmed.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
shirin barzanjeh atri
Position
Instructor MSc
Latest degree
Master
Other areas of specialty/work
Health Promotion
Street address
School of Nursing and Midwifery, South Shariati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5694168451
Phone
+98 41 3475 1706
Fax
+98 41 3479 6969
Email
barzanjehs@tbzmed.ac.ir
Web page address
https://nursing.tbzmed.ac.ir/

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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data sets are to be shared after unidentifiable individuals.
When the data will become available and for how long
Data will become available 6 months after publication.
To whom data/document is available
Data is available for people who working in academic institutions.
Under which criteria data/document could be used
Obligation to observe ethics.
From where data/document is obtainable
barzanjehs@tbzmed.ac.ir
What processes are involved for a request to access data/document
A request to access data/document will be respond during one week.
Comments