The effect of spirituality education on the happiness of postmenopausal women

Protocol summary

Study aim
The effect of spirituality education on the happiness of postmenopausal

Design
After registering eligible individuals, they will be divided into two groups of control and intervention through a random number table.

Settings and conduct
By registering with the selected center, we will register the eligible individuals. First, the questionnaires are completed in two groups separately. Then the spiritual training sessions will be held at the Seven-Cenar Health home during 6 sessions of 90 minutes (number of sessions per week will be agreed upon by participants). Immediately and one month after the completion of the Oxford Happiness Inventory sessions, both groups will be completed.

Participants/inclusion and exclusion criteria
Inclusion criteria include: postmenopausal (at least one year after the last menstruation) and reading and writing literacy. Non-compliance criteria include: having a known mental disorder and mourning experience in the first six months of a relative

Intervention groups
The intervention group will be the group who will receive the training program. Finally, in order to comply with ethical issues, upon completion of the training, the outline will be held in two sessions for the control group.

Main outcome variables
changes of happiness

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20110425006284N14
Registration date: 2019-01-08, 1397/10/18
Registration timing: prospective

Last update: 2019-01-08, 1397/10/18
Update count: 0
Registration date: 2019-01-08, 1397/10/18
Registrant information
Name
Maryam Modarres
Name of organization / entity
Tehran university of Medical sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-22, 1397/04/31
Expected recruitment end date
2018-10-22, 1397/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of spirituality education on the happiness of postmenopausal women

Public title
The effect of spirituality education on the happiness of postmenopausal women

Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The age range is between 50 and 65 years old. Postmenopausal, at least one year after their last menstruation. Having reading and writing skills
Exclusion criteria:
Known as a mental illness. In the first-degree relatives during the past six months, they have a mourning experience.

Age
From 50 years old to 65 years old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 70

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of samples to the intervention and control groups will be random and simple using random numbers. In fact, the selection of the research environment will be made available and the allocation of samples will be done in two groups of intervention and control by simple random method.

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 Tehran university of Medical Sciences Faculty of Nursing and Midwifery and Rehab

Street address
Tehran Province, Tehran, District 6, Nosrat St

City
tehran

Province
Tehran

Postal code
1419733171

Approval date
2018-07-03, 1397/04/12

Ethics committee reference number
IR.TUMS.FNM.REC.1397.033

Health conditions studied

1
Description of health condition studied
Happiness, Menopause

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1
Description
happiness

Timepoint
At the beginning of the study (before the intervention), immediately after the end of the session and one month after the end of the intervention

Method of measurement
Oxford Happiness Inventory

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: First, the demographic information and happiness questionnaire is completed. Then, training sessions on Spirituality will focus on topics such as self-awareness, trust and recourse, patience, forgiveness and sugar during 6 sessions of 90 minutes (number of sessions per week will be agreed upon by participants). Immediately and one month after the completion of the Oxford Happiness Inventory sessions, it will be completed again.

Category
Other

2
Description
Control group: Complete the Oxford Happiness Questionnaire and Demographic Information Questionnaire before the intervention and provide routine care by health personnel, then complete the Oxford Happiness Questionnaire immediately and one month after the end of the intervention. Finally, in order to comply with ethical issues, the outline will be held in two sessions.

Category
N/A

Recruitment centers
Recruitment center

Name of recruitment center
Akbarabad Health Center and its related sites, Affiliated to Tehran University of Medical Sciences

Affiliated to
Tehran University of Medical Sciences

Full name of responsible person
Sima. aghay

Street address
Akbar Abad Center of society of Health, Mahboob mojaz St, Khosh St, Tehran, Iran

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aghaei397@gmail.com

Sponsors / Funding sources

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohamad Ali Sahraeean

Street address
5th floor, Central building of Tehran University of Medical sciences, edge of Qods Av, Keshavarz blvd, Tehran

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tums_edu@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Maryam Modarres

Position
Phd Medical education

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because the results of the statistical survey of the data will be published.

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
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
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

Title and more details about the data/document
The text of the letter of consent form

When the data will become available and for how long
17 July 2018

To whom data/document is available
All students

Under which criteria data/document could be used
Being a student

From where data/document is obtainable
Send an email to aghaei397@gmail.com.

What processes are involved for a request to access data/document
Send student card image to email aghaei397@gmail.com

Comments