Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of corrective movements and Saffron consumption on quality of life and depression of women with Multiple Sclerosis

Protocol summary

Study aim
Determining the effect of Saffron consumption and corrective movements on quality of life and depression of women with Multiple Sclerosis

Design
In this randomized, parallel group clinical trial, 100 included women with MS, will be allocated into three groups of intervention or control, using stratified-block randomization sampling method

Settings and conduct
100 included women with MS, referring to MS association in Khorramabad will be allocated into three groups of intervention (performing corrective movements and taking Saffron, performing corrective movements, taking Saffron) or control. At the beginning of the study, all subjects of the four groups will be asked to complete the research questionnaires including demographic information, Beck Depression Inventory, and the Quality of Life Questionnaire. Then, the intervention groups will be performed described Interventions for twelve weeks. The control group would not receive any intervention from the researcher. After completing the intervention, research questionnaires will be completed and the results will be compared with each other.

Participants/Inclusion and exclusion criteria
Entry conditions: Getting 1 to 4 score of Physical Disability Test, Getting 11 to 30 scores of Beck Depression Inventory, Getting 50 scores of physical and 20 scores of Mental dimensions of the Quality of Life Questionnaire No entry conditions: Pregnancy at the beginning of the study

Intervention groups
Intervention groups: first intervention group: Performing corrective movements three times a week and taking 15 mg Saffron capsule twice a day for twelve weeks; second intervention group: performing corrective movements three times a week for twelve weeks; third intervention group: taking 15 mg Saffron capsule twice a day for twelve weeks Control group: does not receive any intervention from the researcher

Main outcome variables
Depression; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170514033961N4**
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
Mandana Saki

Name of organization / entity
Lorestan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 66 3331 6465

Email address
m.saki@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of corrective movements and Saffron consumption on quality of life and depression of women with Multiple Sclerosis

Public title
Effect of corrective movements and Saffron on Multiple Sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a diagnosis of MS and membership in MS association Getting 1 to 4 score of Physical Disability Test Getting 11 to 30 scores of Beck Depression Inventory Getting 50 scores of physical and 20 scores of Mental dimensions of the Quality of Life Questionnaire Age range between 25 to 45 years
Exclusion criteria:
Pregnancy at the beginning of the study
Age
From **25 years** old to **45 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
Samples with inclusion criteria based on stratified-block randomization will be allocated into three groups of intervention group (Corrective exercises and Saffron consumption; corrective exercises, and Saffron consumption) and control group (without any additional intervention by 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 Lorestan University of Medical Sciences
Street address
Vice chancellor for research and technology, Lorestan University of Medical Sciences, Pardis Campus, Khorramabad-Boroujerd Road, Khorramabad, Lorestan
City
khorramabad
Province
Lorestan
Postal code
681983425
Approval date
2017-02-20, 1395/12/02
Ethics committee reference number
LUMS.REC.1395.209

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
multiple sclerosis

Primary outcomes

1

Description
Depression
Timepoint
At the beginning of the study (before the intervention) and 6 and 12 weeks after the completion of the intervention
Method of measurement
Beck Depression Inventory

2

Description
Quality of life
Timepoint
At the beginning of the study (before the intervention) and 6 and 12 weeks after the completion of the intervention
Method of measurement
Quality of Life Questionnaire (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Performing corrective movements three times a week and taking 15 mg Saffron capsule twice a day for twelve weeks
Category
Treatment - Other

2

Description
Second intervention group: Performing corrective movements three times a week for twelve weeks
Category
Treatment - Other

3

Description
Third intervention group: Taking 15 mg Saffron capsule twice a day for twelve weeks
Category
Treatment - Other

4

Description
Control group: Individuals in this group would not receive any intervention from the researcher and they only will complete the research questionnaires at the beginning and end of the research
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ms association
Full name of responsible person
Mandana Saki
Street address
No. 18, Rose Alley, Enghelab Avenue, Khorramabad, Lorestan
City
khorramabad
Province
Lorestan
Postal code
6819834525
Phone
+98 66 3331 6465
Fax
+98 66 3331 6465
Email
mandana_saki@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Morovat Taheri Kalaani
Street address
Vice chancellor for research and technology, Lorestan University of Medical Sciences, Pardis Campus, Khorramabad-Boroujerd Road, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 3312 0172
Fax
+98 66 3312 0172
Email
edu_res@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mandana Saki
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No. 18, Rose Alley, Enghelab Avenue, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan

Postal code
6819834525
Phone
+98 66 3331 6465
Fax
+98 66 3312 0140
Email
mandana_saki@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mandana Saki
Position
موقعیت شغلی Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No. 18, Rose Alley, Enghelab Avenue, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6819834525
Phone
+98 66 3331 6465
Fax
+98 66 3312 0140
Email
mandana_saki@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mandana Saki
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
No. 18, Rose Alley, Enghelab Avenue, Khorramabad, Lorestan
City
Khorramabad
Province
Lorestan
Postal code
6819834525
Phone
+98 66 3331 6465
Fax
+98 66 3312 0140
Email
mandana_saki@yahoo.com

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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The total potential data will be published after unidentifying individuals in the form of information about the main outcomes.
When the data will become available and for how long
Access period will start since 2019
To whom data/document is available
All researchers, teachers, and medical students can receive the published article from the relevant journal
Under which criteria data/document could be used
Undisclosed data will be available to health science researchers for meta-analysis.
From where data/document is obtainable
Send email to Mandana Saki mandana_saki@yahoo.com
What processes are involved for a request to access data/document
After submitting the document by applicant researcher through email, the data will be sent two weeks later.
Comments