Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation the effect of Jollab beverage on fatigue and happiness in patients with multiple sclerosis referring to the MS Association of Rafsanjan

Protocol summary

Study aim
Determination the effect of Jollab beverage on fatigue and happiness in patients with multiple sclerosis referring to the MS Association of Rafsanjan

Design
A randomized, blinded, sham controlled clinical trial with a parallel group design

Settings and conduct
In this randomized clinical trial, the study population are patients with multiple sclerosis who will referred to M.S association of Rafsanjan. Participants will select by convenience sampling method based on inclusion criteria of the study. Random allocation of the participants will carry out using the minimization method . Participants will be divided into two groups of intervention (will receive Jollab beverage) and control (will receive placebo beverage). Demographic questionnaire and the FSS and Oxford happiness questionnaires are data collection tool which will completed at the before the intervention and 30 days after the intervention in both groups.

Participants/Inclusion and exclusion criteria
Age between 18-60 years old, satisfaction to participate in the study, getting a score above 36 from the Fatigue Severity Scale (FSS) questionnaire, satisfaction for taking Jollab beverage or placebo, confirmation of multiple sclerosis by a neurologist are inclusion criteria. Having other neurological diseases except multiple sclerosis, allergy to medicinal plants especially saffron and rosa damascene, pregnancy and lactation are exclusion criteria.

Intervention groups
Intervention group: In this group, patients will receive 45 ml of jolab beverage (including 10.5 cc rose water, 15 mg saffron, 9.25 g brown sugar and 3.75 cc water) daily for 4 weeks. Control group: In this group, patients will receive placebo (including 13.5 cc water, 1.5 cc rose water, 9.25 g brown sugar and yellow food colour to create a colour similar to the Jollab) exactly like the intervention group

Main outcome variables
Fatigue Happiness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150713023190N12**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **prospective**

Last update: **2022-05-23, 1401/03/02**
Update count: **0**

Registration date
2022-05-23, 1401/03/02

Registrant information

Name
Tabandeh Sadeghi

Name of organization / entity
Rafsanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-05, 1401/03/15

Expected recruitment end date
2022-09-06, 1401/06/15

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

Scientific title
Investigation the effect of Jollab beverage on fatigue and happiness in patients with multiple sclerosis referring to the MS Association of Rafsanjan

Public title
The effect of Jollab beverage on fatigue and happiness in patients with multiple sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-60 years old Satisfaction to participate in the study Getting a score above 36 from the Fatigue Severity Scale questionnaire Satisfaction for taking Jollab beverage or placebo Confirmation of multiple sclerosis by a neurologist
Exclusion criteria:
Having other neurological diseases except multiple sclerosis Allergy to medicinal plants especially saffron and rosa damascena Pregnancy Lactation
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified randomization by minimization method: in this method, initially, the patients will categorize based on key variables, such as scores from fatigue severity scale and Oxford happiness questionnaires. Afterwards, from the patients who will meet the inclusion criteria, the first participant will place in the intervention or control group by coin flip, and other participants will allocate to the study group with lower total of variables. The following table is used as a randomization tool: Variables Category Intervention group Control group Happiness questionnaire score 0-29 30-58 59-87 Fatigue Severity Scale (FSS) questionnaire score 36-49 50-63
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences
Street address
Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2022-04-13, 1401/01/24
Ethics committee reference number
IR.RUMS.REC.1401.015

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
Fatigue
Timepoint
Before the intervention and 30 days after the Jollab beverage consumption
Method of measurement
Fatigue Severity Scale

2

Description
Happiness
Timepoint
Before the intervention and 30 days after the Jollab beverage consumption
Method of measurement
Oxford Happiness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, patients will receive 45 ml of jolab beverage (including 10.5 cc rose , 15 mg saffron, 9.25 g brown sugar and 3.75 cc water) daily for 4 weeks.
Category
Treatment - Other

2

Description
Control group: In this group, patients will receive placebo (including 13.5 cc water, 1.5 cc rose water, 9.25 g. brown sugar and yellow food colour to create a colour similar to the Jollab) exactly like the intervention group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rafsanjan MS association
Full name of responsible person
Fatemeh Ayoubi
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Sponsors / Funding sources

1

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Name of organization / entity
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vcrt@rums.ac
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
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Rafsanjan University of Medical Sciences
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable