

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Dec 2021

### The effect of probiotic *Saccharomyces Bulardi* on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis (MS)

#### Protocol summary

##### Study aim

Determination of the effect of probiotic *Saccharomyces Bulardi* on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis

##### Design

This study is a phase-1, 4-month two arm parallel concealed, randomized, double-blind, placebo-controlled clinical trial among 50 participants with multiple sclerosis. Participants will randomly be divided into two groups to take either probiotic supplements (n D 25) or placebo (n D 25).

##### Settings and conduct

Sampling in this study will be done in a non probable and available way. All participants will be enrolled in the study after description of the methods of study and obtaining written informed consent. General information will be collected using a demographic questionnaire. After taking blood samples from patients and evaluating study variables and randomly entering them into one of two groups, capsules are delivered to people for two weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: multiple sclerosis confirmed by a neurologist; no other chronic diseases; not pregnant; not consuming probiotic foods from a month before the study Exclusion criteria: acute gastrointestinal disease; acute and severe phase of MS

##### Intervention groups

First, all participants would be matched based on body mass index and age. Participants would be then randomly divided into two groups to take either probiotic supplements (n D 25) or placebo (n D 25) for 4 months. In the intervention group (n D 25), participants will receive a probiotic capsule daily for 4 months. The probiotic capsule are contained *Saccharomyces Bulardi*.

##### Main outcome variables

mental health; fatigue, quality of life; pain; inflammatory indices (hs-CRP); Oxidative stress (total antioxidant capacity; superoxide dismutase; Malondialdehyde)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161022030424N1**

Registration date: **2018-04-09, 1397/01/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

##### Registration date

2018-04-09, 1397/01/20

##### Registrant information

##### Name

Neda Dolatkah

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 1928

##### Email address

dolatkahn@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of probiotic Saccharomyces Bulardi on mental health, quality of life, fatigue, pain and indices of inflammation and oxidative stress in Multiple Sclerosis (MS)

**Public title**

The effect of probiotic Saccharomyces Bulardi in Multiple Sclerosis (MS)

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having a disease for more than a year Multiple sclerosis confirmed by a neurologist No other chronic diseases Lack of mental illness Not pregnant Not consuming probiotic foods from a month before the study

**Exclusion criteria:**

Unwillingness to continue studying at each stage Consumption of any probiotic food during the study Acute gastrointestinal disease Antibiotic use during the study Acute and severe phase of MS

**Age**

From **20 years** old to **45 years** old

**Gender**

Both

**Phase**

1

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomizations will be conducted by an assistant using permuted block randomization method and stratified randomization will be used to match participants based on age and body mass index

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

It would be impossible for research personnel involving with participants or analyzing the study results to adjust randomization or discern what product participants were receiving, ensuring true allocation concealment. The placebo is indistinguishable in color, smell and taste from the probiotic capsule.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Regional Ethics Committee for Research (Human Subjects Studies) Tabriz University of Medical Science

**Street address**

Emam Reza Hospital, Golgasht, Azadi Avenue.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163995479

**Approval date**

2017-10-02, 1396/07/10

**Ethics committee reference number**

IR.TBZMED.REC.1396.592

**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**

mental health

**Timepoint**

Determining mental health at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

**Method of measurement**

General Health Questionnaire (GHQ-28)

**2****Description**

quality of life

**Timepoint**

Determining quality of life at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

**Method of measurement**

SF-36 quality of life questionnaire

### 3

#### **Description**

pain

#### **Timepoint**

Determining pain at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

#### **Method of measurement**

visual analogue scale

### 4

#### **Description**

fatigue

#### **Timepoint**

Determining fatigue at the beginning of the study (before the intervention) and 2 and 4 months after starting the administration of probiotic or placebo supplementation

#### **Method of measurement**

fatigue severity scale (FSS)

### 5

#### **Description**

hs-CRP inflammatory index

#### **Timepoint**

Determining hs-CRP inflammatory index at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

#### **Method of measurement**

biochemical assay

### 6

#### **Description**

total antioxidant capacity (TAC)

#### **Timepoint**

Determining total antioxidant capacity (TAC) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

#### **Method of measurement**

biochemical assay

### 7

#### **Description**

superoxide dismutase (SOD)

#### **Timepoint**

Determining superoxide dismutase (SOD) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

#### **Method of measurement**

biochemical assay

### 8

#### **Description**

malondialdehyde (MDA)

#### **Timepoint**

Determining malondialdehyde (MDA) at the beginning of the study (before the intervention) and 4 months after starting the administration of probiotic or placebo supplementation

#### **Method of measurement**

biochemical assay

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Probiotic capsule containing 250 mg yeast of *Saccharomyces boulardii* (1010 CFU) and 100 mg of magnesium and lactose stearates daily after a meal, for 4 months manufactured by a TakGene Zist (Tehran, Iran)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo capsule containing 100 mg of magnesium and lactose stearates daily after a meal, for 4 months manufactured by a TakGene Zist (Tehran, Iran)

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Emam Reza Hospital

##### **Full name of responsible person**

Neda Dolatkhan

##### **Street address**

Azadi, Golgasht

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Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5163995479

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+98 41 3336 1928

##### **Email**

dolatkahn@tbzmed.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Neda Dolatkhah

**Street address**

Azadi, Golgasht

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**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**

Neda Dolatkhah

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Neda Dolatkhah

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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Physical Medicine and Rehabilitation Dept., Emam Reza Hospital, Golgasht, Azadi Ave.

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Neda Dolatkhah

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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

**Data Dictionary**

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