

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effects of *Melissa officinalis* on Stress, Anxiety, Depression, sleep disturbances and Compassion Fatigue among Nurses Caring for COVID-19 Patients

#### Protocol summary

##### Study aim

Determining the effects of melissa officinalis on stress, anxiety, depression, sleep disorders and compassion fatigue among Nurses Caring for COVID-19 Patients

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase three on 88 nurses, for randomization, Android Statistics and sample size software will be used.

##### Settings and conduct

The researcher will refer to Ayatollah Rouhani Hospital in Babol and coronavirus patients' wards, and the nurses will be selected according to their inclusion and randomization criteria based on Android statistical software. Questionnaires will be completed (demographic characteristics, stress, anxiety and depression, Petersburg sleep quality, and compassion fatigue). Nurses in the experimental group will be given lemon balm tea and the placebo group will be given black tea twice a day (morning and evening) for 21 days after the intervention (for twenty-one days or three weeks) again in the fourth week. The mentioned questionnaires will be completed by the nurses of both groups and will be collected with the help of the researcher in different shifts. Nurses and researchers will be blind to the type of tea consumed.

##### Participants/Inclusion and exclusion criteria

At least a degree in nursing: Having one year of work experience and at least six months of care for coronavirus patients: No history of asthma, allergies, and chronic diseases: Lack of stressful events in the last three months.

##### Intervention groups

Nurses in the experimental group will be given lemon balm tea in a 3-gram bag from Newsha twice (morning and evening) for 21 days. Nurses of the placebo group will be given black tea in the form of a 3 gram bag (Tea-

bag) from Newsha twice (morning and evening) for 21 days

##### Main outcome variables

Determining the level of stress, anxiety, depression in nurses

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190204042617N2**

Registration date: **2021-06-30, 1400/04/09**

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

Last update: **2021-06-30, 1400/04/09**

Update count: **0**

##### Registration date

2021-06-30, 1400/04/09

##### Registrant information

##### Name

Parvin Aziznejadroshan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 0597

##### Email address

aziznejadroshan@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of Melissa officinalis on Stress, Anxiety, Depression, sleep disturbances and Compassion Fatigue among Nurses Caring for COVID-19 Patients

**Public title**

The effects of Melissa officinalis on Stress, Anxiety, Depression, sleep disturbances and Compassion Fatigue among Nurses

**Purpose**

Supportive

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

Having at least a degree in nursing : Having one year of work experience : At least six months of care for hospitalized patients with coronavirus

**Exclusion criteria:**

Have a history of asthma, allergies, and chronic diseases : Stressful events such as divorce and the death of loved ones for any reason in the past three months

**Age**

From **23 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **88**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be performed using the permutation block method. In this study, the size of each block is considered 4. Each block will have an equal number of intervention and control groups (2 from each) in random order. Randomization is written by a statistician and sample size expert using Android software. Similar envelopes will be considered for the number of nurses. The type of intervention will be written inside each envelope. The number of orders will be written on the envelopes. After entering the study, one of these envelopes will be assigned to each of the nurses and the relevant code will be recorded in the checklist.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both tea bags of lemon balm and black tea will be similar in appearance, size and weight (3 grams) and will be unknown from Newsha products and the type of bags. The nurses studied will not be aware of the type of tea. The researcher will be blind to the type of tea consumed

for each nurse.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Babol University of Medical Sciences

**Street address**

Ganj Afrooz, Babol University of Medical Sciences

**City**

Babol

**Province**

Mazandaran

**Postal code**

47176-47745

**Approval date**

2021-05-31, 1400/03/10

**Ethics committee reference number**

IR.MUBABOL.REC.1400.107

**Health conditions studied****1****Description of health condition studied**

Stress

**ICD-10 code**

F43

**ICD-10 code description**

Reaction to severe stress, and adjustment disorders

**2****Description of health condition studied**

Anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**3****Description of health condition studied**

sleep disorders

**ICD-10 code**

F51

**ICD-10 code description**

Sleep disorders not due to a substance or known physiological condition

## 4

### **Description of health condition studied**

sleep disorders

### **ICD-10 code**

G47

### **ICD-10 code description**

Sleep disorders

## 5

### **Description of health condition studied**

sleep disorders

### **ICD-10 code**

G47.2

### **ICD-10 code description**

Circadian rhythm sleep disorders

## 6

### **Description of health condition studied**

Stress

### **ICD-10 code**

F43.0

### **ICD-10 code description**

Acute stress reaction

## **Primary outcomes**

### 1

#### **Description**

Stress score on DASS-21

#### **Timepoint**

At the beginning of the study and 21 days after starting to consume lemon balm

#### **Method of measurement**

DASS-21 questionnaire

### 2

#### **Description**

Anxiety score on DASS-21

#### **Timepoint**

At the beginning of the study and 21 days after starting to consume lemon balm

#### **Method of measurement**

DASS-21 questionnaire

### 3

#### **Description**

Depression score on DASS-21

#### **Timepoint**

At the beginning of the study and 21 days after starting to consume lemon balm

#### **Method of measurement**

DASS-21 questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Sleep Disorders Score

#### **Timepoint**

At the beginning of the study and 28 days after giving lemon balm tea

#### **Method of measurement**

Petersburg Sleep Quality Questionnaire

### 2

#### **Description**

Compassion fatigue score

#### **Timepoint**

At the beginning of the study and 28 days after giving lemon balm tea

#### **Method of measurement**

Figley Compassion Fatigue Questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: Nurses will be given lemon balm tea in the form of a 3 gram bag from Newsha twice (morning and evening) for 21 days.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: Nurses will be given black tea in the form of a 3 gram bag (Tea-bag) from Newsha company twice (morning and evening) for 21 days.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Ayatollah Rouhani Hospital of Babol

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

Dr. Seyed Ebrahim Hejazian

##### **Street address**

Kargar Square, Ganj Afrooz Street, Ayatollah Rouhani Hospital

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

47176-47745

##### **Phone**

+98 11 3223 8301

##### **Fax**

##### **Email**

rohani@mubabol.ac.ir

**Web page address**

<https://publicrelations.mubabol.ac.ir/page/?id=615>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

**Street address**

Gangafros

**City**

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**Province**

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**Phone**

+98 11 3219 7667

**Email**

rezaghadimi@yahoo.com

**Web page address**

<http://research.mubabol.ac.ir/>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol University of Medical Sciences

**Proportion provided by this source**

50

**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**

Babol University of Medical Sciences

**Full name of responsible person**

Parvin Aziznejadroshan

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

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**Full name of responsible person**

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

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**City**

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**Province**

Mazandaran

**Postal code**

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**Phone**

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**Email**

aziznejadroshan@yahoo.com

## 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**

With the official consent of the Research Deputy of Babol  
University of Medical Sciences

### **Study Protocol**

No - There is not a plan to make this available

### **Statistical Analysis Plan**

Not applicable

### **Informed Consent Form**

No - There is not a plan to make this available

### **Clinical Study Report**

Not applicable

### **Analytic Code**

Not applicable

### **Data Dictionary**

Not applicable