

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

Babol

Province

Mazandaran

Postal code

47176-47745

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

Street address

Gangafros

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 0597

Email

aziznejadroshan@yahoo.com

Person responsible for scientific 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

Street address

Gangafros

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 2597

Email

aziznejadroshan@yahoo.com

Person responsible for updating data**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

Street address

Gangafros

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 0597

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