Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+98 11 3219 0597
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
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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
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Person responsible for updating data

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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