

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of the effect of aromatherapy with Citrus Aurantium and foot reflexology on sleep quality and physiological index in patients with heart failure in cardiac care units

#### Protocol summary

##### Study aim

Comparison of the effect of aromatherapy with Citrus Aurantium and foot reflexology on sleep quality and physiological index in patients with heart failure in cardiac care units

##### Design

This is a randomized clinical trial, were randomly assigned into three groups (based on odd and even case number) of orange blossom essential oil aromatherapy, foot reflexology, and control.

##### Settings and conduct

in patients with heart failure hospitalized in the CCU of Ahvaz educational hospitals

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent to Participate in Research; Final diagnosis of heart failure in grade two and three by the cardiologist; With EF 20-40%; Age of people 40 to 65 years; Awareness of time, place, and persons and no history of known mental and psychiatric disorders; No allergy to essences; No history of peripheral neuropathy, venous thrombosis, and foot disability, and lack of open wound on reflex points; Physical ability to adopt the desired body postures during the intervention (massage); No use of complementary medicine methods within a week.

##### Intervention groups

In the aromatherapy intervention group, the subjects inhaled a sterilized napkin impregnated with three drops of orange blossom essential oil (Vareth Pharmaceutical Research Complex) approved by the Medicinal Herbs Research Center of the Jundishapur Ahvaz Medical Sciences University, with three deep breaths at 10 PM in three consecutive days. In the reflexology group, the intervention was performed by the researcher on female subjects and by a male assistant on male subjects according to the Manual Reflexology Method of Fr. Josef Eugster based on the Ingham method in the bed in a

private room to create an atmosphere of confidence. Reflexology was performed in three days for 30 min (15 min on each foot).

##### Main outcome variables

sleep quality; physiological parameters

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180601039930N1**

Registration date: **2018-10-14, 1397/07/22**

Registration timing: **retrospective**

Last update: **2018-10-14, 1397/07/22**

Update count: **0**

##### Registration date

2018-10-14, 1397/07/22

##### Registrant information

##### Name

Elahe Qayem

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 6702

##### Email address

qayem.e@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-22, 1397/04/31

##### Expected recruitment end date

2018-08-22, 1397/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of aromatherapy with Citrus Aurantium and foot reflexology on sleep quality and physiological index in patients with heart failure in cardiac care units

**Public title**

Comparison of the effect of aromatherapy with Citrus Aurantium and foot reflexology on sleep quality and physiological index in patients with heart

**Purpose**

Supportive

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

Conscious Consent to Participate in Research Final diagnosis of heart failure in grade two and three by the cardiologist With EF 20-40% Age of people 40 to 65 years Knowledge of time and place and the absence of known mental and psychiatric disorders

**Exclusion criteria:**

having allergies to essential oils Lack of peripheral neuropathy, venous thrombosis, organ failure in open-sided open-stenosis at the reflexion site Physical ability to be in the desired conditions for intervention: Massage. use of a variety of complementary medicine methods within a week

**Age**

From **40 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **123**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization using random numbers table After obtaining written consent, the patients were randomly assigned into three groups; two intervention groups and one control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

•Ethics committee of Ahvaz University of Medical Sciences

**Street address**

, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Approval date**

2018-05-11, 1397/02/21

**Ethics committee reference number**

IR.AJUMS.REC.1397.123

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

heart failure

**ICD-10 code**

I50

**ICD-10 code description**

Heart failure

**Primary outcomes****1****Description**

sleep quality

**Timepoint**

Reflexology was performed in three days for 30 min (15 min on each foot).

**Method of measurement**

Pittsburgh standard sleep quality questionnaire (PSQI)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: 1-orange blossom essential oil aromatherapy: In the aromatherapy intervention group, the subjects inhaled a sterilized napkin impregnated with three drops of orange blossom essential oil (Vareth Pharmaceutical Research Complex) approved by the Medicinal Herbs Research Center of the Jundishapur Ahvaz Medical Sciences University, with three deep breaths at 10 PM in three consecutive days

**Category**

Rehabilitation

**2****Description**

Intervention group: In the reflexology group, the intervention was performed by the researcher on female subjects and by a male assistant on male subjects according to the Manual Reflexology Method of Fr. Josef Eugster based on the Ingham method in the bed in a private room to create an atmosphere of confidence. Reflexology was performed in three days for 30 min (15 min on each foot).

**Category**

Rehabilitation

**3****Description**

Control group: The control group received only the routine care of the ward in similar conditions with no intervention

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

in the CCU of Ahvaz educational hospitals

**Full name of responsible person**

Habib hey bor

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itc@ajums.ac.ir

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badawi

**Street address**

, Jundishapur University of Medical Sciences, Ahvaz, Iran

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ahvaz

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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**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Nasrin Elahi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Amineh qayem

**Position**

MSc of Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Amineh qayem

**Position**

MSc of Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

A portion of the data is disseminated after being unidentified.

**When the data will become available and for how long**

Get started since 2018

**To whom data/document is available**

Researchers working in academia and academia

**Under which criteria data/document could be used**

If referenced to the results of the research can be used.

**From where data/document is obtainable**

Corresponding Author Email

**What processes are involved for a request to access data/document**

After a week, agreement will be sent to your emails.

**Comments**