Clinical Trial Protocol
Iranian Registry of Clinical Trials

Investigating the effect of citrus aurantium on job Burnout neurological functions and happiness in pre hospital emergency personal

Protocol summary

Study aim
Investigating the effect of citrus aurantium on job Burnout neurological functions and happiness in pre hospital emergency personal

Design
Participants in the five morning shifts (8-20) will be randomized during the two weeks under the citrus aurantium or water treatment. Occupational burnout and happiness measure before and after the intervention on the first day and after the last intervention and one week after the last intervention. However, neurological functions are measured every intervention day (5 shifts) before and after the intervention.

Settings and conduct
The site of this study is Sabzevar Urban and Road Emergency stations

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having nursing, anesthesiology, operating room technician, rescue and emergency medicine Activities in pre-hospital emergency (operational) Inclination in research Healthy sense of smell Have at least one year of work experience Not having a history of asthma and allergies Do not use sedative medications during the last month No disaster occurred within a month before intervention No use of perfume at the time of study Lack of colds B. Exclusion criteria: Unwillingness to continue participating in research Feeling sick or sensitive to the smell of essential oil Catching cold

Intervention groups
In the test group, the aroma of essential oil is 10% and using a pendant neck with a distance of about 20 cm from the nose and containing 1.5 cc of essential oil. In the control group, using a pendant neck with a distance of about 20 cm from the nose and containing 1.5 cc of water is done

Main outcome variables
Burnout Happiness Cognitive Neuroscience Functions

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20110430006342N9
Registration date: 2019-02-10, 1397/11/21
Registration timing: registered_while_recruiting

Last update: 2019-02-10, 1397/11/21
Update count: 0

Registration date
2019-02-10, 1397/11/21

Registrant information
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Name of organization / entity
Semnan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-04, 1397/11/15

Expected recruitment end date
2019-07-06, 1398/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty
Scientific title
Investigating the effect of citrus aurantium on job Burnout .neurological functions and happiness in pre hospital emergency personal

Public title
The effect of citrus aurantium on job Burnout .neurological functions and happiness

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Having nursing, anesthesiology, operating room technician, rescue and emergency medicine Activities in pre-hospital emergency Inclination in research Healthy sense of smell Have at least one year of work experience Not having a history of asthma and allergies Do not use sedative medications during the last month No disaster occurred within a month before intervention No use of perfume at the time of study Lack of colds

Exclusion criteria:
Unwillingness to continue participating in research Feeling sick or sensitive to the smell of essential oil Catching cold

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Using six blocks (randomly selected from six possible blocks), individuals are randomly divided into two groups.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Deputy of research and technology, Central Headquarters of Semnan University of Medical Sciences, Basij Boulevard

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Semnan

Province
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Postal code
3519899951

Approval date
2019-01-15, 1397/10/25

Ethics committee reference number
IR.SEMUMS.REC.1397.262

Health conditions studied

1
Description of health condition studied
Occupational Burn-out

ICD-10 code
Z73.0

ICD-10 code description
Burn-out

Primary outcomes

1
Description
Burnout score in Maslach questionnaire

Timepoint
Before and after interventions on the first day and after the last intervention and one week after the last intervention

Method of measurement
Maslach Burnout Questionnaire

2
Description
Happiness score in the Oxford questionnaire

Timepoint
Before and after interventions on the first day and after the last intervention and one week after the last intervention

Method of measurement
Oxford questionnaire

3
Description
Cognitive Neuroscience Functions

Timepoint
All intervention days (5 shifts) before and after intervention

Method of measurement
Stroop test
Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: Aromatherapy will be done by 10% essential oil and using a pendant neck, containing 1.5 cc of essential oil, prepared from the Essential Oil Barium, during the shifts (12 hours). The distance to the nose is about 20 cm
Category
Treatment - Other

2
Description
Control group: Using a pendant neck, a container containing 1.5 cc of water, is carried out during the shift (12 hours). Its distance to the nose is about 20 cm apart
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Pre-hospital emergency
Full name of responsible person
Seid Hamid Zia
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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
Not applicable

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