Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Influence of omega-3 fatty acids in health care providers suffering from occupational burnout on symptoms of burnout, and saliva cortisol secretion – a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim
Effect of omega-3 fatty acids on nursing burnout and salivary cortisol levels
Design
randomized ,double blind ,parallel, Clinical trials with control group
Settings and conduct
Occupational burnout nurses are randomly divided into two groups using colored card envelopes and treated with 100 mg of omega-3 or placebo for 8 weeks.
Participants/Inclusion and exclusion criteria
Burnout nurses who have written written consent to the study and received no supplementary medication in the last three months.
Intervention groups
The intervention group received omega-3 capsules and the control group received placebo capsules
Main outcome variables
Maslach Burnout Questionnaire, salivary cortisol levels

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090304001743N14**
Registration date: **2018-06-04, 1397/03/14**
Registration timing: **prospective**

Last update: **2018-06-04, 1397/03/14**
Update count: **0**
Registration date
2018-06-04, 1397/03/14

Registrant information
Name
Mohammad Haghighi
Name of organization / entity
Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-23, 1397/07/01
Expected recruitment end date
2019-01-21, 1397/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Influence of omega-3 fatty acids in health care providers suffering from occupational burnout on symptoms of burnout, and saliva cortisol secretion – a randomized, double-blind, placebo-controlled clinical trial

Public title
Influence of omega-3 fatty acids on health care provider burn out
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
diagnosis of burnout Written consent

Exclusion criteria:
Use of complementary medications in the last three months

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
30 red cards and 30 blue cards are placed in a non-transparent packets, Each person picks up a packet, Each color is considered for a group

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, placebo, which is precisely in the form of a drug product, is administered randomly to the patients and explained to the patients that he or she may receive a drug or placebo. Therefore, the patient and the clinical caregiver are not aware of the type of product.The other person other than the investigator is responsible for the preparation of the drug and placebo boxes and the researcher is not aware of it. The investigator of the outcome is also unaware of the type of product.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Fahmideh Bulvar.Mahdieh street

City
Hamadan

Province
Hamadan

Postal code
65178

Approval date
2018-04-22, 1397/02/02

Ethics committee reference number
IR.UMSHA.REC.1397.1

Health conditions studied

1

Description of health condition studied
Occupational Burnout

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Maslach Burnout Questionnaire score

Timepoint
Before the intervention, 4 weeks and 8 weeks after the intervention

Method of measurement
Maslach Burnout Questionnaire

2

Description
saliva cortisol

Timepoint
Before the intervention and 8 weeks after the intervention

Method of measurement
Cortisol Saline Measure Kit

Secondary outcomes

1

Description
Beck Depression Inventory score

Timepoint
Before the intervention,4weeks and 8 weeks after intervention

Method of measurement
Beck Depression Inventory

2

Description
Insomnia Severity Index score

Timepoint
Before the intervention,4weeks and 8 weeks after intervention

Method of measurement
Insomnia Severity Index

Intervention groups

1

Description
Intervention group: Omega-3 capsules at a dose of 1000 mg daily for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule daily for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Mohammad haghighi
Street address
Dibaj Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Mohammad Haghighi
Position
Preofessor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Ahmadpanah

Position

Associate professor of Psycology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Not applicable

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

Not applicable