

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 4184

Email address

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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 haghghi

Street address

Dibaj Street

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65175

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haghghi@umsha.ac.ir

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 Haghghi

Position

Preofessor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Haghghi

Position

Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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 Psychology

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