

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effect of education-based intervention on rate of adherence of patients with suspected sleep apnea to physician's order for sleep test

Protocol summary

Study aim

The aim of this study is evaluation of the effect of education-based intervention on rate of adherence of patients with suspected sleep apnea to physician's order for sleep test.

Design

100 patients among all patients who will be visited by related physicians in Isar, Sajjad, and Ebn'e Sina clinics and some physicians' private practices and meet the entry criteria will be selected and assigned randomly to the intervention and control groups. Educational material required for patients with suspected sleep apnea is provided using the educational resources available in the field of sleep disorders and experts consensus. The provided content is implemented as a booklet and video and will be provided to patients in the intervention group. A multi-center, double-blinded 2-armed randomized control trial is designed to evaluate the effectiveness of education-based intervention.

Settings and conduct

Patients who will be visited by related physicians in Isar, Sajjad, and Ebn'e Sina clinics and some physicians' private practices and meet the entry criteria will be selected and assigned randomly to the intervention and control groups. In this study, the care providers, outcome assessor, and data analyser will not aware of the group to which any patient belongs.

Participants/Inclusion and exclusion criteria

Physician's order for sleep test and baseline literacy have been considered as major inclusion criteria. Unwillingness to stay in the study has been considered as the major exclusion criterion.

Intervention groups

The intervention group will use a booklet and video containing disease and diagnosis points for a period of one month. The control group will not receive designed education-based intervention.

Main outcome variables

Referral rate for sleep test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170922036314N3**

Registration date: **2018-02-09, 1396/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

Shokoufeh Aalaei

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2429

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aalaeish931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2018-02-09, 1396/11/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of education-based intervention on rate of adherence of patients with suspected sleep apnea to physician's order for sleep test

Public title
Evaluation of the effect of education-based intervention on referral rate of patients with suspected sleep apnea for sleep test

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Physician's order for sleep test baseline literacy
Exclusion criteria:
Unwillingness to stay in the study.

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

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization: simple randomization; Unit of randomization: individual randomization; the tool use in randomization: sealed envelopes; the random sequence will be built using www.randomization.com website

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the care providers, outcome assessor, and data analyser will not aware of the group to which any patient belongs.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Medicine Ethical Committee
Street address
Faculty of Medicine, Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
917-7948-564
Approval date
2017-02-22, 1395/12/04
Ethics committee reference number
IRCT2017092236314N1

Health conditions studied

1

Description of health condition studied
sleep apnea
ICD-10 code
G47.3
ICD-10 code description
Sleep apnoea

Primary outcomes

1

Description
Referral rate for sleep test
Timepoint
1 month after the intervention
Method of measurement
checklist

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will use a booklet and video containing disease and diagnosis points for a period of one month.
Category
Behavior

2

Description
The control group will not receive designed education-based intervention.
Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Sajjad occupational medicine center

Full name of responsible person

Dr. Lahya Afshari Saleh

Street address

2th East Amin Street, Sajjad Blvd.

City

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9186600000

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2

Recruitment center

Name of recruitment center

Isar Clinic

Full name of responsible person

Dr. Mahnaz Amini

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Imam Khomeini Street

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3

Recruitment center

Name of recruitment center

Ebn'e Sina Hospital

Full name of responsible person

Dr. Hadi Asadpour

Street address

Horeameli Avenue, Mashhad

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4

Recruitment center

Name of recruitment center

Doctor's office

Full name of responsible person

Dr. Hadi Asadpour

Street address

Ahmadabad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh Ebrahimzadeh

Street address

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EbrahimzadehF2@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Student Research Committee, Department of Medical Informatics, School of Medicine, Mashhad University

Full name of responsible person

Shokoufeh Aalaei

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Medical Informatics

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Person responsible for updating data

Contact

Name of organization / entity

Student Research Committee, Department of Medical Informatics, School of Medicine, Mashhad University

Full name of responsible person

Shokoufeh Aalaei

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Saeid Eslami

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Other areas of specialty/work

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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

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