

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

A comparison of the effect of mobile-based and paper-based educational interventions on knowledge of patients with obstructive sleep apnea

Protocol summary

Summary

The aim of this study is a comparison of the effect of mobile-based and paper-based educational interventions on knowledge of patients with obstructive sleep apnea. Using of any type of positive airway pressure (PAP) device for treatment at the time of the study, baseline literacy, having a smartphone and Lack of some underlying diseases have been considered as major inclusion criteria. Unwillingness to stay in the study have been considered as the major inclusion criterion. 90 patients among all patients who underwent the sleep study in Emam Reza, Ebn'e Sina, and Razavi Hospitals, Roya, and Sabz Darman sleep clinics and meet the entry criteria will be selected and assigned randomly to the intervention and control groups. Educational material required for obstructive sleep apnea patients 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 a mobile-based application. The booklet will be provided to all patients and the mobile application will just 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 the mobile-based application. Patients' knowledge as the primary outcome will be evaluated by a questionnaire before and 1 month after intervention. PAP usage will be also assessed as the secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092236314N1**

Registration date: **2017-10-21, 1396/07/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-21, 1396/07/29

Registrant information

Name

Shokoufeh Aalaei

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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aalaeish931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research of Mashhad University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-02-04, 1396/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of mobile-based and paper-based educational interventions on knowledge of patients with obstructive sleep apnea

Public title

Evaluation of educational interventions on knowledge of patients with obstructive sleep apnea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: All patients with obstructive sleep apnea that use any type of positive airway pressure device; Baseline literacy; having a smartphone (the patient or first-degree relatives); Lack of some underlying diseases such as dementia and visual impairment 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

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Postal code

Approval date

2017-02-22, 1395/12/04

Ethics committee reference number

IR.MUMS.fm.REC.1395.571

Health conditions studied

1

Description of health condition studied

obstructive sleep apnea

ICD-10 code

G47.3

ICD-10 code description

Sleep apnoea

Primary outcomes

1

Description

patients' knowledge level about disease and treatment

Timepoint

pre intervention, 1 month after the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

PAP (positive airway pressure) usage rate

Timepoint

pre intervention, 1 month after the intervention

Method of measurement

usage data stored on PAP (positive airway pressure) device

Intervention groups

1

Description

The intervention group will use a booklet and a mobile-based application containing disease and treatment points for a period of one month.

Category

Behavior

2

Description

The control group will use a booklet containing educational content for a period of one month.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Mahnaz Amini

Street address

Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

City

Mashhad

2

Recruitment center

Name of recruitment center

Ebn'e Sina Hospital

Full name of responsible person

Dr. Hadi Asadpour

Street address

Horeameli Avenue, Mashhad, Iran

City

Mashhad

3

Recruitment center

Name of recruitment center

Razavi Hospital

Full name of responsible person

Dr. Hadi Asadpour

Street address

After Qaem Bridge, Azadi Highway ,Mashhad ,Iran

City

Mashhad

4

Recruitment center

Name of recruitment center

Roya sleep clinic

Full name of responsible person

Dr. Hadi Asadpour

Street address

Parastar Street, Mashhad

City

Mashhad

5

Recruitment center

Name of recruitment center

Sabz Darman sleep clinic

Full name of responsible person

Dr. Mehri Sarfarazi

Street address

Kouhsangi Avenue, Mashhad, Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fahimeh Ebrahimzadeh

Street address

Mashhad University of Medical Sciences

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Shokoufeh Aalaei

Position

Ph.D student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Departments of Medical Informatics, School of Medicine, Mashhad University of Medical Sciences, Mash

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty