

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The role of liaison nurse on satisfaction, therapeutic adherence and sleep quality on hypertensive patients referring to a hypertension clinic

Protocol summary

Study aim

Determining the role of the liaison nurse in patient satisfaction, treatment adherence, and sleep quality among patients with hypertension attending a hypertension clinic

Design

A clinical trial with intervention and control groups, with parallel groups, without blinding, due to the lack of a similar study, initially 30 people are enrolled in a pilot study. Then, using its information in the formula for comparing two independent groups, the final sample size is estimated and the study continues until it is achieved. The sealed envelope site will be used for randomization.

Settings and conduct

This study is a randomized clinical trial with a pre-test and post-test design. The study population is hypertensive patients living in Semnan and referring to the blood pressure clinic of Kosar Hospital, Semnan. The intervention includes education on the concept of hypertension, lifestyle modification, the correct use of medications, and the correct measurement of blood pressure.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 40 - 60 years old; ability to read and write, ability to understand and respond to questionnaire items, presence of sleep problems, defined as a Pittsburgh Sleep Quality Index (PSQI) score greater than 5, treatment adherence of less than 50%. Exclusion Criteria: withdrawal from continued cooperation with the liaison nurse, failure to respond to telephone calls, hospitalization of the patient, and death of the patient.

Intervention groups

The intervention group, receives education on hypertension, medication use, and lifestyle modification from a liaison nurse, along with a home-care pamphlet. The control group receives the same education and pamphlet after the study.

Main outcome variables

Satisfaction, Adherence, Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110427006318N18**

Registration date: **2026-02-17, 1404/11/28**

Registration timing: **prospective**

Last update: **2026-02-17, 1404/11/28**

Update count: **0**

Registration date

2026-02-17, 1404/11/28

Registrant information

Name

Monir Nobahar

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 23 3365 4190

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-04, 1405/01/15

Expected recruitment end date

2027-09-06, 1406/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of liaison nurse on satisfaction, therapeutic adherence and sleep quality on hypertensive patients referring to a hypertension clinic

Public title

The role of liaison nurse on satisfaction, therapeutic adherence and sleep quality on hypertensive patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 40 - 60 years old Ability to read and write Ability to understand and respond to questionnaire items Presence of sleep problems, defined as a Pittsburgh Sleep Quality Index (PSQI) score greater than 5 Treatment adherence of less than 50% Willingness to participate in the study and to sign the informed consent form Not being a member of healthcare staff No routine use of antidepressant, anti-anxiety, sedative, or analgesic medications Definitive diagnosis of hypertension, defined as a chronic blood pressure of $\geq 140/90$ mmHg Having access to a mobile phone or a landline telephone

Exclusion criteria:

Withdrawal from continued collaboration with the liaison nurse Failure to respond to telephone calls Hospitalization of the patient Death of the patient

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients referred to the blood pressure clinic of Semnan Kosar Hospital will be included in the study using a convenience sampling method. At the beginning of the work, we will randomly determine which letter A or B represents the intervention or control group by using a coin toss. In the next step, using the Sealed envelope website (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) and using the Restricted Randomization method with blocks of six, the patients will be randomly divided into two groups A and B. In other words, for every six patients who enter the study consecutively, 3 people will be randomly placed in group A and 3 people in group B. We write the letters A and B of the random sequence generated by the software on pieces of paper and place them inside sealed envelopes. We open the envelopes in order of patients entering the clinic and assign the individual to the relevant group based on their content.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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 Science

Street address

Faculty Nursing and Midwifery, Semnan University of Medical Sciences, Semnan

City

Semnan

Province

Semnan

Postal code

3513138111

Approval date

2026-01-14, 1404/10/24

Ethics committee reference number

IR.SEMUMS.REC.1404.253

Health conditions studied**1****Description of health condition studied**

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Satisfaction

Timepoint

Before and one month after discharge

Method of measurement

Wolf Patients Satisfaction Instrument

Secondary outcomes**1****Description**

Adherence

Timepoint

Before and one month after discharge

Method of measurement

Treatment adherence in patients with chronic disease
Modanloo

2**Description**

Sleep quality

Timepoint

Before and one month after discharge

Method of measurement

Pittsburg Sleep Quality Index (PSQI)

Intervention groups**1****Description**

Intervention group: In this group, at the beginning of the study, patients who meet the conditions for inclusion in the study are given sufficient explanations about the method and objectives of the study. After obtaining oral and written informed consent, they complete the demographic information questionnaires, Wolf patient satisfaction, treatment adherence in patients with chronic diseases Modanloo, and the Pittsburgh Sleep Quality Index. Then, during a 15-minute session, they are taught the concept of hypertension, lifestyle modification, the correct way to take medications, and how to correctly measure blood pressure. Then, an educational pamphlet for home care is provided to the patient. From the time of referral until one month later, the liaison nurse will be in contact with the patients in the intervention group by telephone and provide the necessary guidance and answer their questions. One month after referral, they complete the satisfaction, treatment adherence, and sleep quality questionnaires again.

Category

Lifestyle

2**Description**

Control group: In this group, at the beginning of the study, patients who meet the conditions for inclusion in the study are given sufficient explanations about the method and objectives of the study. After obtaining oral and written informed consent, they complete the demographic information questionnaires, Wolf patient satisfaction, treatment adherence in patients with chronic diseases Modanloo, and the Pittsburgh Sleep Quality Index. This group is not given any training. One month after their referral, they complete the satisfaction, treatment adherence, and sleep quality questionnaires again. In order to comply with ethics in research in the control group, after the end of the study, they are taught the concept of hypertension, lifestyle modification, the correct way to take medications, and how to correctly measure blood pressure. Then, an educational pamphlet for home care is provided to the patient.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kosar Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Semnan 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

Semnan 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data is confidential

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