Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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 sealedenvelope 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

Email address
Nobahar43@Yahoo.com

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 ≥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 Sealedenvelope 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
Monir Nobahar
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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

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Monir Nobahar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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