

# Research on the application of continuous nursing in postoperative rehabilitation of patients with lower extremity varicose veins

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<b>Registration date</b> 13/11/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/11/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to investigate the effectiveness of a continuous nursing model in the postoperative rehabilitation of patients with lower extremity varicose veins.

### Who can participate?

Patients diagnosed with lower extremity varicose veins who are undergoing surgical treatment, aged between 18 and 75 years old

### What does the study involve?

A control group will receive standard postoperative care, and an experimental group will receive a continuous nursing intervention. The control group's care includes routine wound care, standard discharge instructions, and follow-up appointments as per hospital protocol.

### What are the possible benefits and risks of participating?

Implementing a continuous nursing model may enhance the postoperative rehabilitation and overall well-being of patients with lower extremity varicose veins.

No risk factors.

### Where is the study run from?

Vascular Surgery, Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences

### When is the study starting and how long is it expected to run for?

January 2023 to December 2023

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Junxia Du, [dujunxia2024djx@126.com](mailto:dujunxia2024djx@126.com)

# Contact information

## Type(s)

Public, Scientific, Principal investigator

## Contact name

Dr Junxia Du

## ORCID ID

<https://orcid.org/0009-0008-6603-8593>

## Contact details

Shanxi Academy of Medical Sciences, No. 99 Longcheng Street, Longcheng Street, Xiaodian District  
Taiyuan  
China  
030032  
+86 15234049172  
dujunxia2024djx@126.com

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

Nil known

# Study information

## Scientific Title

Research on the application of continuous nursing model in postoperative rehabilitation of patients with lower extremity varicose veins

## Study objectives

Implementing a continuous nursing model may significantly enhance the postoperative rehabilitation and overall well-being of patients with lower extremity varicose veins.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 10/04/2024, Ethics Committee of Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences (No. 99 Longcheng Street, Longcheng Street, Xiaodian District, Taiyuan, 030032, China; 8603518379145; dyyllwyh@163.com), ref: YXLL-2024-076

## **Study design**

Single-center interventional double-blind randomized trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Lower extremity varicose veins

## **Interventions**

A total of 120 patients meeting the inclusion criteria were recruited for the study. Sample size calculation was based on previous studies, assuming a medium effect size with a power of 0.80 and a significance level of 0.05. Participants were randomly assigned to either the control group (n=60) or the experimental group (n=60) using a computer-generated randomization sequence. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes.

The control group received standard postoperative care, and the experimental group received a continuous nursing intervention. The control group's care included routine wound care, standard discharge instructions, and follow-up appointments as per hospital protocol. The experimental group received a comprehensive intervention comprising five key components:

1. Pre-discharge education covering recovery information, wound care techniques, and activity guidelines
2. A home-based care plan featuring personalized exercise regimens, dietary recommendations, and compression therapy guidance
3. Scheduled follow-ups including weekly telephone consultations and bi-weekly home visits for the first month, followed by monthly visits for two months, plus 24/7 hotline access
4. Psychological support with regular mental health assessments and provision of coping strategies
5. Lifestyle modification guidance for long-term recurrence prevention and occupational adaptations, if necessary

## **Intervention Type**

Mixed

## **Primary outcome(s)**

1. Wound healing time (in days) measured using data recorded in patient medical notes after surgery
2. Lower extremity function was measured using the Lower Extremity Functional Scale (LEFS) scores at 1, 3, and 6 months post-surgery
3. Pain was measured using the Visual Analog Scale (VAS) at 1 month post-surgery
4. Walking distance (in meters) measured using the standardized 6-minute walk test (6MWT) conducted in a 30-meter indoor corridor at 1-month post-surgery. Patients walked at their self-selected pace for 6 minutes with the total distance recorded.
5. Quality of life measured using the Short Form-36 (SF-36) questionnaire scores at 6 months post-surgery

## **Key secondary outcome(s)**

1. Psychological status, measured using Beck Depression Inventory (BDI) scoring and Self-Rating Anxiety Scale (SAS) scoring at 6 months post-surgery
2. Activities of daily living measured using Activities of Daily Living (ADL) at 1, 3, and 6 months post-surgery

**Completion date**

31/12/2023

## Eligibility

**Key inclusion criteria**

1. Patients diagnosed with lower extremity varicose veins who are undergoing surgical treatment
2. Aged between 18 and 75 years
3. Willing and able to provide informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

All

**Total final enrolment**

120

**Key exclusion criteria**

1. Presence of severe comorbidities (such as uncontrolled diabetes or severe cardiovascular disease)
2. Cognitive impairments that could interfere with following postoperative instructions
3. Participation in other clinical trials
4. Pregnancy or breastfeeding

**Date of first enrolment**

20/01/2023

**Date of final enrolment**

10/12/2023

# Locations

## Countries of recruitment

China

## Study participating centre

**Shanxi Bethune Hospital Shanxi Academy of Medical Sciences**

No. 99 Longcheng Street, Longcheng Street, Xiaodian District

Taiyuan

China

030032

# Sponsor information

## Organisation

Shanxi Academy of Medical Sciences

## ROR

<https://ror.org/04tshhm50>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The data that support the findings of this study are available from the corresponding author upon reasonable request, Junxia Du, [dujunxia2024djx@126.com](mailto:dujunxia2024djx@126.com).

## IPD sharing plan summary

Available on request