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Effect of evidence-driven computerised rule-guided exercise prescription combined with closed-loop remote supervision

Submission date
13/07/2026

Recruitment status
Recruiting

Registration date
15/07/2026

Overall study status
Ongoing

Last Edited
14/07/2026

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Lower extremity arteriosclerosis obliterans LEASO disease is a common peripheral arterial disorder. Even after surgical vessel opening, there is still a relatively high risk of re-narrows. The traditional routine exercise rehabilitation program is too homogeneous, and during the patients' home exercise period, there is a lack of continuous supervision, poor exercise execution, and continuous decline in exercise compliance, making it difficult to effectively maintain long-term vascular patency. This study will evaluate the effects of evidence-driven computer rule-guided exercise prescription combined with closed-loop remote supervision on the vascular patency rate, exercise compliance, ABI, self-management ability, quality of life, intervention satisfaction, ultrasound hemodynamic indicators, and re-intervention rate in patients with LEASO, providing a reference for the construction of a standardized, intelligent, and scalable postoperative rehabilitation model for LEASO.

Who can participate?
All patients aged over 45 years, diagnosed with LEASO, presenting with Fontaine grade II intermittent claudication, who have completed endovascular intervention or open bypass surgery, are conscious and able to operate WeChat to complete communication and check-in, can apply to participate in this study.

What does the study involve?
Eligible patients will be randomly assigned to one of the two groups. Patients in the control group will receive routine post-surgery exercise guidance, including a paper-based exercise manual, posture demonstration by nurses during hospitalisation, exercise key point reminders at discharge and one telephone follow-up at 1 month after surgery. Patients in the study group will obtain a fully customized exercise prescription automatically generated by the system that matches their personal physical condition, and join a dedicated management WeChat group. Nurses send daily exercise reminders, patients upload exercise data after completing training, medical staff will follow up the exercise situation in real time, dynamically adjust the exercise programme according to the patient's recovery status, and arrange regular offline re-examinations at the hospital as scheduled. The intervention of both groups lasts for 3 months

after surgery, and the follow-up continues until 6 months after surgery. During the period, multiple lower extremity vascular ultrasound examinations, ankle-brachial index measurements and questionnaire assessments will be conducted to evaluate the rehabilitation status.

What are the possible benefits and risks of participating?
Participation in this study offers intervention group patients individualized exercise prescriptions tailored to their age, cardiac function, ankle-brachial index and other characteristics, plus whole-process remote supervision, resulting in higher vascular patency rates and ankle-brachial indices at 3 and 6 months postoperatively, lower target vessel reintervention rates, better exercise compliance, self-management ability, quality of life and intervention satisfaction. No severe exercise-related adverse events occurred in either group, with only a few cases of mild limb soreness that resolved spontaneously. Potential risks include mild exercise-related discomfort; the intervention group bears the time and operational burden of daily check-ins and 6 offline follow-up visits within 3 months postoperatively, plus minimal privacy risks associated with health data sharing. The control group, receiving only one telephone follow-up at 1 month postoperatively, faces a potential risk of undetected asymptomatic restenosis.

Where is the study run from?
Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences, Third Hospital of Shanxi Medical University, Tongji Shanxi Hospital, China.

When is the study starting and how long is it expected to run for?
The recruitment of the first participants began in March 2026. The entire study is expected to take approximately 12 months, and all data collection work will be completed by February 2027.

Who is funding the study?
Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences, Third Hospital of Shanxi Medical University, Tongji Shanxi Hospital, China.

Who is the main contact?
Yuan Bai, yuanbai_by56@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

XX grant number
YS-2025-HL-033

Study information

Scientific Title
Effect of evidence-driven computerised rule-guided exercise prescription combined with closed-loop remote supervision on vascular patency and exercise compliance after lower extremity arteriosclerosis obliterans surgery

Study objectives
To explore the efficacy of evidence-based computerized rule-guided individualized exercise prescription combined with closed-loop remote supervision on vascular patency, exercise compliance, clinical outcomes, adverse events and reintervention rates in patients after lower extremity arteriosclerosis obliterans (LEASO) surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/03/2026, Medical Ethics Committee of the Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences (No. 99, Longcheng Street, Taiyuan, Shanxi, 030032, China; +86 0351-8379146; wsdyp1994@163.com), ref: YXLL-2026-056

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Postoperative exercise rehabilitation intervention for postoperative patients with lower extremity arteriosclerosis obliterans and Fontaine ischemia grade II

Interventions
This is a prospective, single-centre, parallel-group randomized controlled trial. A random sequence was generated using SPSS version 26.0. The allocation results of the groups were concealed using sealed opaque envelopes. 88 patients were randomly divided into the study group and the control group at a 1:1 ratio according to the random number table, with 44 patients in each group.

The control group receives routine exercise guidance covering the preoperative, in-hospital, discharge and post-discharge stages: preoperatively, the responsible nurse provides oral health education and distributes a paper-based general exercise manual; during postoperative hospitalisation, the responsible nurse demonstrates core exercises such as ankle pump exercises and basic walking one-on-one to the patients; at discharge, the key points of home exercise are re-emphasized to patients and their families, and only one telephone follow-up is conducted at 1 month after surgery, without additional exercise reminders, check-in supervision or programme adjustments.

The study group receives the combined intervention of evidence-driven computerised rule-guided exercise prescription and closed-loop remote supervision, based on the high-quality rehabilitation evidence systematically searched from Chinese and English databases between January 2020 and December 2025, two rounds of Delphi expert consultation and patient demand interviews. A rule-based computerised clinical decision support system based on a WeChat mini-programme is built. After inputting individual patient data, including age, New York Heart Association cardiac function class, ABI, maximum preoperative walking distance, postoperative wound healing and postoperative recovery stage, the system automatically generates a staged and individualised exercise prescription, which is embedded with a safety constraint threshold alarm mechanism, and all automatically generated prescriptions need to be reviewed and confirmed by clinicians. The whole-process closed-loop remote management is implemented via WeChat groups, each management unit contains 10 patients, assigned to one responsible nurse and one vascular surgeon. Nurses send daily exercise reminders at 8:00 am and 3:00 pm. Patients upload their actual exercise duration and step frequency data after completing exercise, and nurses review all check-ins daily and provide targeted guidance to patients who do not meet the requirements. The exercise programme is dynamically adjusted based on patient feedback and weekly offline follow-up results to ensure the safety and effectiveness of the whole intervention. The intervention lasts for 3 months postoperatively, and follow-up continues until 6 months after surgery.

Intervention Type
Behavioural

Primary outcome(s)
1. 6-month vascular patency rate after surgery measured using colour Doppler ultrasound to detect the proportion of patients with unobstructed vessels, defined as stenosis <50% in morphology and peak systolic velocity ratio PSVR <2.0 in haemodynamics, at 6 months after surgery

Key secondary outcome(s)

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Patients who met the diagnostic criteria for LEASO, presented with a Fontaine ischaemia grade of II (intermittent claudication) and had undergone an endovascular intervention or open bypass surgery
2. Aged ≥45 years
3. With a preoperative ABI ranging from 0.4 to 0.9
4. Who were conscious, able to partake in basic communication and able to operate WeChat
5. Whose participation was voluntarily and who were able to complete follow-up

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
56 Years

Upper age limit
76 Years

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Patients with severe cardiac, pulmonary, hepatic or renal dysfunction
2. With a malignant tumour, abnormal coagulation function or active bleeding
3. With a lower extremity deformity or severe osteoarthritis affecting walking
4. With cognitive dysfunction or mental illness
5. Who were unable to cooperate with the intervention or complete data collection
6. With critical limb ischaemia of Fontaine grades III or IV
7. Who withdrew from the study or discontinued the intervention during the research period

Date of first enrolment
18/03/2026

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Shanxi Academy of Medical Sciences

ROR
https://ror.org/04tshhm50

Funder(s)

Funder type

Funder Name
Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences, Third Hospital of Shanxi Medical University, Tongji Shanxi Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Yuan Bai, yuanbai_by56@163.com.

IPD sharing plan summary
Available on request