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Clinical effects of mobile app (Keep)–based exercise management in patients with diabetic peripheral neuropathy

Submission date
21/11/2026

Recruitment status
No longer recruiting

Registration date
25/11/2026

Overall study status
Completed

Last Edited
23/11/2026

Condition category
Nervous System Diseases

[ ] 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
Diabetic peripheral neuropathy is a common complication of diabetes that affects the nerves, most often in the feet and legs. It can cause symptoms such as pain, numbness, tingling, weakness, and problems with balance and walking. Regular exercise may help reduce symptoms and improve health, but many people find it difficult to maintain an exercise programme on their own. This study aims to find out whether a mobile phone app called Keep can support people with diabetic peripheral neuropathy to follow a structured exercise programme and improve their nerve symptoms, blood sugar control, physical function, quality of life, and exercise habits.

Who can participate?
Adults aged 18 to 65 years with type 2 diabetes and mild to moderate diabetic peripheral neuropathy can take part. Participants must be using exercise infrequently, be able to use a smartphone, complete study questionnaires independently, and provide written informed consent.

What does the study involve?
A total of 72 participants take part in the study. Participants are enrolled into two groups at different times. One group receives usual care, which includes routine treatment, nursing care, health education about diet, exercise and medication monitoring, and weekly telephone follow-up calls.
The second group receives the same usual care plus a 12-week exercise management programme delivered through the Keep mobile app. The programme includes aerobic and resistance exercises performed three times per week, with each session lasting about 50 minutes. Participants also receive exercise guidance, daily reminders through WeChat, and weekly telephone calls from the research team. Exercise intensity is adjusted during the programme according to participants' progress.
Researchers assess participants at the start of the study and again during and after the programme. They measure nerve symptoms, blood sugar levels, mobility, quality of life, and how closely participants follow their exercise programme.

What are the possible benefits and risks of participating?
Participants in the exercise programme may experience improvements in their nerve symptoms, physical function, blood sugar control, quality of life, and ability to maintain regular exercise. The information gained may also help improve future care for people with diabetic peripheral neuropathy.
As with any exercise programme, there is a possibility of discomfort, tiredness, muscle soreness, or minor exercise-related injuries. To reduce these risks, participants receive guidance and regular monitoring throughout the programme. People with medical conditions that could make exercise unsafe are not eligible to take part.

Where is the study run from?
The study is run from Hebei University of Chinese Medicine in Shijiazhuang, China.

When is the study starting and how long is it expected to run for?
April 2025 to June 2026.

Who is funding the study?
The study is funded by the Social Science Fund of Hebei Province (Project No. HB23SH016).

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Clinical effects of mobile app (Keep)–based exercise management in patients with diabetic peripheral neuropathy: a nonrandomized, non-concurrent controlled quasiexperimental study

Study objectives
To evaluate the association between a 12-week mobile platform (Keep app)-supported exercise management program and neuropathy severity in patients with diabetic peripheral neuropathy (DPN). Secondary objectives include assessing the effects of the program on glycemic control, lower-extremity functional mobility, quality of life, and self-reported exercise adherence.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/03/2025, Medical Ethics Committee of Hebei University of Chinese Medicine (No. 3 Xingyuan Road, Luquan District, Shijiazhuang, 050200, China; +86 18903118985; 463771448@qq.com), ref: YXLL202503001

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Diabetic peripheral neuropathy

Interventions
Control group:
Participants received usual care, including routine treatment, nursing care, and routine health education on diet, exercise, and medication monitoring. They also received weekly telephone follow-ups.

Intervention group:
In addition to usual care, participants received a 12-week comprehensive exercise management program delivered via the Keep mobile app. The program consisted of combined aerobic and resistance exercise (3 sessions per week, 50 minutes per session, including warm-up, aerobic exercise, resistance exercise, and cool-down). It also included professional guidance during hospitalization, daily WeChat reminders, and weekly telephone follow-up to monitor progress and adjust exercise intensity every 4 weeks.

Intervention Type
Behavioural

Primary outcome(s)
1. Neuropathy severity measured using Toronto Clinical Scoring System (TCSS) score (range 0 to 19; higher scores indicate more severe neuropathy) at baseline, week 4, and week 12

Key secondary outcome(s)
1. Fasting plasma glucose measured using blood glucose meter (mmol/L) at baseline and week 12

2. Glycated hemoglobin A1c (HbA1c) measured using glycated hemoglobin analyzer (%) at baseline and week 12

3. Lower-extremity functional mobility measured using Timed Up and Go (TUG) test (seconds) at baseline, week 4, and week 12

4. Neuropathy-related quality of life measured using Norfolk Quality of Life Questionnaire-Diabetic Neuropathy (QOL-DN) score at baseline, week 4, and week 12

5. Self-reported exercise adherence measured using exercise adherence scale developed by Weng (2014) (score range 15 to 60) at baseline, week 4, and week 12

Completion date

30/06/2026

Eligibility

Key inclusion criteria
1. Age between 18 and 65 years
2. Clinically diagnosed with type 2 diabetes and mild to moderate diabetic peripheral neuropathy (DPN)
3. Low usual exercise frequency (less than 3 sessions per week, with each session lasting less than 20 minutes)
4. Proficiency in operating a smartphone and ability to complete questionnaires independently
5. Provision of signed written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Type 1 diabetes mellitus or gestational diabetes mellitus
2. Coexisting autonomic neuropathy or upper extremity neuropathies/lesions
3. Presence of severe complications or other contraindications to exercise (e.g., acute diabetic complications, deep vein thrombosis, or diabetic foot ulcers)
4. Coexisting severe organ dysfunction (e.g., cardiac, pulmonary, hepatic, or renal failure) or severe cerebrovascular disease
5. Concurrent participation in other interventional clinical trials

Date of first enrolment
01/04/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
China

Study participating centre
Hebei University of Chinese Medicine
China

Sponsor information

Organisation
Hebei University of Chinese Medicine

ROR
https://ror.org/02qxkhm81

Funder(s)

Funder type

Funder Name
Social Science Fund of Hebei Province (Project No. HB23SH016)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available