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Generative artificial intelligence support for self-management in adults with type 2 diabetes

Submission date
02/11/2026

Recruitment status
Recruiting

Registration date
03/11/2026

Overall study status
Ongoing

Last Edited
03/11/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
People with type 2 diabetes need ongoing support with daily self-management. This study will assess whether JARVIS, an generative artificial intelligence (AI) intervention using the application and a smart ring, improves blood sugar control over 6 months. It will compare usual care with the AI intervention, with or without additional personalised support from community diabetes management staff. The study will also examine implementation, acceptability and cost-effectiveness.

Who can participate?
Adults aged 18–70 years with type 2 diabetes who receive care at community health service centres, can use a smartphone and the study devices, and meet the study eligibility criteria.

What does the study involve?
Community health service centres will be randomly assigned to one of three groups: usual diabetes care; usual care plus the AI application and smart ring; or the same digital intervention with additional personalised support from community diabetes management staff.
Both intervention groups will receive training and usage reminders. The application will use health information, activity and sleep data, and participant records to personalise daily tasks and update plans.
Participants will take part for 6 months and attend assessments at baseline, 3 months and 6 months, including blood tests, body measurements and questionnaires.

What are the possible benefits and risks of participating?
Participants may improve their understanding of diabetes and daily self-management, although benefits are not guaranteed. Possible risks include discomfort from ring wear, the time required to participate, inaccurate AI advice and privacy risks. Participants will receive guidance and support.

Where is the study run from?
Peking University, Guangdong Second Provincial General Hospital and Sun Yat-sen University, in collaboration with participating community health service centres and stations in Guangzhou, China.

When is the study starting and how long is it expected to run for?
November 2026 to May 2027

Who is funding the study?
The National Natural Science Foundation of China

Who is the main contact?
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Study information

Scientific Title
Effectiveness of just-in-time adaptive, ring-informed generative AI support for self-management (JARVIS) in adults with type 2 diabetes: a three-arm pragmatic cluster-randomized controlled trial

Acronym
JARVIS

Study objectives
The primary objective is to evaluate the effectiveness of JARVIS, a just-in-time adaptive, ring-informed generative AI intervention, with or without additional health-coach support, in reducing HbA1c from baseline to 6 months among adults with type 2 diabetes, compared with usual community-based diabetes care.

Secondary objectives are to assess effects on body weight, waist circumference, self-management behaviours, self-efficacy, exercise, sleep and health-related quality of life.

The study will also include a process evaluation examining intervention implementation, participant engagement and acceptability, and an economic evaluation assessing the cost-effectiveness of the interventions compared with usual community-based diabetes care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/08/2026, Peking University Institutional Review Board (38 Xueyuan Road, Beijing, 100191, China; +86 (0)10-82805751; llwyh@bjmu.edu.cn), ref: IRB00001052-26128

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment

Parallel

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The study will use cluster randomisation, with community health service centres or stations as the units of randomisation. An independent statistician who is not involved in participant recruitment or outcome assessment will use a computer-generated random allocation sequence to assign clusters in a 1:1:1 ratio to usual care, usual care plus the GenAI intervention, or usual care plus the GenAI intervention and additional personalised human support. All enrolled participants within each centre or station will receive the intervention allocated to that cluster. The intervention and follow-up period for each participant will be 6 months.

Arm 1: Usual care
Participants will receive usual community-based diabetes care provided by family doctors or general practitioners. This includes routine follow-up, health education, dietary and physical-activity advice, medication management, blood-glucose monitoring advice and referral when clinically indicated. Participants will not receive the study application, smart-ring intervention or additional structured support specified for the intervention groups.

Arm 2: Usual care plus the GenAI-enabled self-management intervention
In addition to usual care provided by family doctors or community outpatient general practitioners, participants will receive a 6-month generative artificial intelligence (GenAI)-enabled self-management intervention delivered through the application and a smart ring. The intervention will be implemented by designated community diabetes management staff responsible for the routine management of patients with diabetes at the participating community health service centre. These staff will provide individual baseline training covering application installation and registration, smart-ring pairing and wear, use of the self-management modules, completion of daily tasks and access to technical assistance. They will also provide periodic refresher training and usage reminders throughout the intervention. Personalised self-management guidance and feedback will be delivered through the GenAI system.
The intervention provides just-in-time adaptive support by integrating smart-ring data, participant records and feedback to personalise daily tasks, update self-management plans and automatically trigger tailored prompts and recommendations.

Arm 3: Usual care plus the GenAI-enabled self-management intervention and human support
Participants will receive the same usual care, GenAI intervention, baseline training, periodic refresher training and usage reminders as those in Arm 2, implemented by designated community diabetes management staff.
In addition, these staff will provide personalised reinforcing feedback at scheduled stages throughout the intervention. Drawing on each participant’s progress, application and smart-ring engagement, and reported difficulties, they will help participants understand and apply AI-generated recommendations, review progress towards individual goals, reinforce successful behaviours and address barriers to self-management.

Intervention Type
Mixed

Primary outcome(s)
1. Glycated haemoglobin (HbA1c) measured using clinical assessments at baseline, 3 and 6 months

Key secondary outcome(s)
1. Smart-ring wear adherence measured using the proportion of intervention days with valid wear data obtained from device records at continuously during the intervention

2. Device-measured physical activity and sleep measured using mean daily step count and mean nightly sleep duration obtained from valid smart-ring records at continuously during the intervention

3. Application engagement measured using the proportion of assigned daily tasks recorded as completed obtained from application backend logs at continuously during the intervention

4. Diabetes self-efficacy, self-management behaviours and diabetes-related emotional distress measured using the 8-item Diabetes Self-Efficacy Scale (DSES), and domain scores of the Summary of Diabetes Self-Care Activities (SDSCA), and the 2-item Diabetes Distress Scale (DDS-2) at baseline, 3 and 6 months

5. Self-reported physical activity, sleep quality and medication adherence measured using the International Physical Activity Questionnaire–Short Form (IPAQ-SF), the Pittsburgh Sleep Quality Index (PSQI) and the 5-item Medication Adherence Report Scale (MARS-5), respectively, at baseline, 3 and 6 months

6. Body weight and waist circumference measured using a weighing scale in kilograms and a measuring tape in centimetres, respectively, at baseline, 3 and 6 months

7. Healthcare utilisation and costs measured using a structured questionnaire recording outpatient visits, emergency department visits, hospital admissions, inpatient days and associated healthcare expenditure at baseline, 3 and 6 months

8. Health-related quality of life measured using EQ-5D questionnaire at baseline, 3 and 6 months

Completion date
30/05/2027

Eligibility

Key inclusion criteria
1. Diagnosed with type 2 diabetes mellitus by a medical institution
2. Aged 18–70 years, inclusive
3. Currently receiving diabetes health-management services at a participating community health service centre
4. Has basic smartphone skills and is able to use the study application and devices
5. Able and willing to complete the scheduled follow-up assessments, questionnaires and clinical measurements
6. Willing to participate and able to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Type 1 diabetes, gestational diabetes or another specific type of diabetes
2. Severe cognitive impairment, dementia or a severe mental disorder
3. Severe cardiovascular or cerebrovascular disease, end-stage kidney disease, severe liver dysfunction, malignant tumour or another serious condition that may make participation unsafe or unsuitable
4. A recent severe acute complication of diabetes
5. Planning to relocate or otherwise unlikely to complete the scheduled follow-up assessments
6. Currently participating in another clinical or intervention study that may interfere with the intervention, outcome assessment or participation in the present study
7. Considered by the investigator to be unable to participate safely or to comply with the study procedures

Date of first enrolment
01/11/2026

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
National Natural Science Foundation of China

ROR

https://ror.org/01h0zpd94

Funder(s)

Funder type

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available