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Promoting universal eye health coverage through integrating eye care into primary health care system in rural Xinjiang, China

Submission date 16/05/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/05/2025	**Overall study status** Ongoing	
Last Edited 16/05/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

Vision impairment and blindness are significant health challenges in rural areas of Xinjiang, China, where access to eye care is limited. This study aims to test a new approach, the iREACHES model, which combines health system strengthening (HSS) and behavioral economics (BE) strategies to improve access to eye care services. We will evaluate whether the model helps more people use primary eye care (PEC) services and get timely referrals for specialist care when needed.

Who can participate?

Adults aged 18 years or older who live in the rural communities served by the participating township health centers (THCs) in Shawan County and Jinghe County, Xinjiang, and have lived there for at least six months. Participants must be able to give informed consent and must not have received eye treatment in the two weeks prior to the study.

What does the study involve?

Participants will receive improved eye care services at their local health centers. The intervention includes better training for healthcare providers, community education about eye health, and more effective referral pathways to specialist care when necessary. Some participants will receive the new eye care model earlier than others as the program is gradually introduced.

What are the possible benefits and risks of participating?

The potential benefits include better access to eye care services, improved vision-related quality of life, and greater awareness of eye health. There is a minimal risk of discomfort during eye examinations or sharing personal health information, but all procedures will follow ethical guidelines to ensure participant safety.

Where is the study run from?

The study will be conducted in township health centers (THCs) in Shawan County and Jinghe County, located in rural Xinjiang, China.

When is the study starting and how long is it expected to run for?
September 2024 to May 2026

Who is funding the study?
The study is funded by the Peking University (China)

Who is the main contact?
For more information, please contact the Principal Investigator at Peking University.
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Promoting universal eye health coverage through integrating eye care into primary health care in rural Xinjiang, China: a stepped wedge cluster randomized trial and macroeconomic modelling study

Acronym
iREACHES

Study objectives
The primary hypothesis of this study is that the iREACHES model, which integrates health system strengthening (HSS) and behavioral economics (BE) strategies, will significantly improve: (1) Utilization of primary eye care (PEC) services at township health centers (THCs) in rural Xinjiang compared to usual care; and (2) Referral efficiency to secondary eye care (SEC) at county hospitals for conditions requiring specialized treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 12/05/2025, Peking University Institutional Review Board Office (38 Xueyuan Road, Haidian District, Beijing, 100191, China; +(86)010-82805751; llwyh@bjmu.edu.cn), ref: IRB00001052-25041

2. Approved 05/12/2024, Medical Ethics Management Committee of Jinghe County People's Hospital (No. 19 Jianshe Road, Jinghe County, Bortala Mongol Autonomous Prefecture, Xinjiang, 833300, China; +(86)0909-5332366; 1214995717@qq.com), ref: JHIRB2024001

3. Approved 31/12/2024, Medical Ethics Committee of Shawan People's Hospital (62 Century Avenue South Road, Shawan City, Tacheng Prefecture, Xinjiang, 834700, China; +(86)0993-6011362; 15981701234@163.com), ref: SWIRB2024001

Study design
Multicenter interventional stepped-wedge cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Diagnostic, Prevention, Screening, Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
The study focuses on improving access to primary eye care (PEC) and referral efficiency for secondary eye care (SEC) to address vision impairment and blindness among rural residents in Xinjiang, China.

Interventions
The study will implement the iREACHES model, which integrates Health System Strengthening (HSS) and Behavioral Economics (BE) strategies, in 16 township health centers (THCs) across two rural counties in Xinjiang. The intervention will include:
Systemic Integration of Eye Care: Incorporating eye disease screening into routine health examinations and strengthening referral pathways.
Capacity Building: Training healthcare providers through a "train-the-trainer" model and equipping THCs with essential diagnostic tools.
Strengthening Continuity of Care: Enhancing the coordination between primary and secondary eye care within the County-level Tight Medical Alliances (CTMAs).
Improving Eye Health Literacy: Conducting community education campaigns and employing behavioral nudges to encourage eye care utilization.
Participants will be randomized at the cluster level using a stepped-wedge design, with one cluster transitioning from control to intervention every three months. Usual care will serve as the control, comprising routine health services without the iREACHES-specific interventions. The duration of the intervention will be 12 months, and data collection will take place at three-month intervals to monitor primary and secondary outcomes.

Intervention Type
Mixed

Primary outcome measure
1. Utilization of PEC services at township health centers is measured using healthcare facility records at baseline and 12 months post-intervention
2. Number of appropriate referrals to secondary eye care at county hospitals is measured using referral logs and hospital health information systems at baseline and 12 months post-intervention

Secondary outcome measures
1. Availability of trained personnel, diagnostic tools, and screening capabilities at PHC level is measured using facility audits and healthcare provider surveys at baseline and 12 months post-intervention
2. Community knowledge about eye health is measured using structured interviews and community surveys at baseline and 12 months post-intervention
3. Vision-related quality of life is measured using the NEI VFQ-25 at baseline and 12 months post-intervention
4. General health-related quality of life is measured using the EQ-5D-5L at baseline and 12 months post-intervention

Overall study start date
01/09/2024

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Residents of rural communities served by the participating township health centers (THCs) in Shawan County and Jinghe County, Xinjiang
3. Individuals who have resided in the local community for at least six months prior to the study
4. Individuals who are willing and able to provide informed consent
5. Individuals who have not received ophthalmological treatment within two weeks prior to the study
6. Individuals without severe cognitive impairments or other conditions that would hinder their ability to provide informed consent

Participant type(s)
Resident

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The target number of participants for this multicenter stepped-wedge cluster randomized controlled trial (SW-CRT) is 1,120 individuals, with 14 clusters (township health centers) and 80 participants per cluster.

Key exclusion criteria
1. Individuals who have received ophthalmological treatment within two weeks prior to the study
2. Individuals with severe cognitive impairments that hinder the ability to provide informed consent
3. Individuals with medical conditions that may interfere with participation or outcome assessment
4. Individuals who do not reside in the rural areas served by the selected township health centers (THCs) in Shawan County or Jinghe County, Xinjiang
5. Individuals under 18 years of age
6. Individuals who have not lived in the local community for at least six months prior to the study

Date of first enrolment
20/05/2025

Date of final enrolment
20/05/2026

Locations

Countries of recruitment
China

Study participating centre
Peking University
38 Xueyuan Road, Haidian District
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100191

Study participating centre
Jinghe County People's Hospital
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Study participating centre
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Funder(s)

Funder type
University/education

Funder Name
Peking University

Alternative Name(s)
, PKU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available upon request from the Principal Investigator at Peking University. Requests for data access should be directed to Xiaochen Ma, Assistant Professor
China Center for Health Development Studies, Peking University, Beijing, China.
xma@hsc.pku.edu.cn.

Data Types to Be Shared
The shared data will include de-identified individual participant data (IPD) related to eye care service utilization, referral efficiency, and vision-related quality of life (VRQoL), collected during the trial.

Availability Timeline
Data will be available starting six months after publication of the primary results and will remain accessible for a period of five years.

Access Criteria and Mechanism
Data will be shared with researchers affiliated with academic or public health institutions who provide a methodologically sound proposal. Data access will be granted for the purpose of replicating results, conducting meta-analyses, or exploring secondary research questions related to rural eye care and health systems strengthening.

Ethical and Legal Considerations
The data will be anonymized to protect participant confidentiality, and data sharing will comply with ethical guidelines and data protection regulations. Participants will provide informed consent, including their agreement to data sharing under these conditions.

Mechanism for Data Access
Approved researchers will be required to sign a data-sharing agreement outlining the terms of use, including prohibition of data re-identification and commitment to publish findings in peer-reviewed journals.

IPD sharing plan summary
Available on request