

Diagnostic Performance of an AI-based Model for TCM Constitution Classification Using Ophthalmic Imaging

NCT07127939

Status	RECRUITING
Sponsor	Second Affiliated Hospital of Nanchang University
Enrollment	1,024 participants

Key Eligibility Criteria

Inclusion (11)

- Age: Participants aged between 18 and 60 years;
- Chronic Systemic Diseases: Defined according to the standards of the United States National Center for Chronic Disease Prevention and Health Promotion and the "Healthy China 2030" planning outline issued by the State Council. These are characterized as conditions lasting one year or longer that require continuous medical care, limit daily activities, or both. The four major chronic diseases in China include: Cardiovascular and cerebrovascular diseases, Malignant neoplasms, Diabetes mellitus and Chronic respiratory diseases;
- Cardiovascular and Cerebrovascular Diseases: This category includes: Hypertension: Stable hypertension without acute episodes, defined as systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg, or currently undergoing antihypertensive treatment. Coronary Heart Disease: Diagnosed based on a history of coronary heart disease or confirmed through imaging evidence such as coronary angiography or CT angiography.
- Heart Failure: Classified as New York Heart Association (NYHA) functional class II-IV with a left ventricular ejection fraction $< 40\%$. Stroke: Diagnosed based on a history of ischemic or hemorrhagic stroke or confirmed through imaging evidence such as MRI or CT scans;
- Malignant Neoplasms: Participants with newly diagnosed, recurrent, metastatic malignant tumors, or those currently receiving specific treatments (e.g., chemotherapy, radiotherapy, immunotherapy), confirmed by histological or cytological examinations;
- ... and 6 more (see full listing online)

Exclusion (4)

- Incomplete Clinical Data Supporting Diagnosis: Participants for whom the clinical data necessary to substantiate the diagnosis are incomplete;
- Significant Opacification of Other Ocular Optical Systems: Individuals presenting with pronounced obscurations in other ocular optical systems (e.g., severe corneal opacification, nuclear cataract grade IV or higher, severe vitreous hemorrhage or opacification) that impede the completion of comprehensive ocular examinations;
- Acute Systemic Organic Diseases: Patients concurrently suffering from acute systemic organic conditions (such as acute infections or decompensated organ failure) that prevent participation in the constitution identification procedures;
- Pregnancy or Lactation: Individuals who are pregnant or currently breastfeeding.

Locations (1 total)

The Second Affiliated Hospital of Nanchang University, Nanchang, Jiangxi, China

<https://clinicaltrials.gov/study/NCT07127939>

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