ISRCTN11483487 https://doi.org/10.1186/ISRCTN11483487

Comparing augmented reality glasses with a physical brain model to help patients and families understand the risks of planned brain surgery

Submission date
16/01/2026

Recruitment status
No longer recruiting

Registration date
13/02/2026

Overall study status
Completed

Last Edited
20/04/2026

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Principal investigator

Contact name
Prof Zhanxiang Wang

ORCID ID
https://orcid.org/0000-0003-0405-6194

Contact details
The First Affiliated Hospital of Xiamen University
School of Medicine
Xiamen University
No. 55 Zhenhai Road
Siming District
Xiamen
China
361001
+86 (0)15587331975
WangZX@xmu.edu.cn

Type(s)
Scientific

Contact name
Dr Zhengbo Yuan

ORCID ID
https://orcid.org/0000-0002-9337-9544

Contact details
The First Affiliated Hospital of Xiamen University
School of Medicine
Xiamen University
No. 55 Zhenhai Road, Siming District
Xiamen
China
361001
+86 (0)15154608303
24520240157824@stu.xmu.edu.cn

Additional identifiers

Study information

Scientific Title
Comparing augmented reality glasses with a physical brain model to help patients and families understand the risks of planned brain surgery

Study objectives
To determine whether head-mounted augmented reality visualization using individualized three-dimensional models during routine preoperative counseling improves objective and self-reported understanding of surgical risks in patients (and/or legally authorized representatives) scheduled for elective cranial neurosurgery for intracranial space-occupying lesions, compared with counseling aided by a physical anatomical model. Secondary objectives are to compare post-counseling anxiety, communication satisfaction, consultation duration, and clinician communication performance assessed using the SEGUE framework based on video-recorded consultations.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/11/2025, Ethics Committee of the First Affiliated Hospital of Xiamen University (No. 55 Zhenhai Road, Siming District, Xiamen, 361003, China; +86 (0)592-2132222, +86 (0) 15154608303; 1125073977@qq.com), ref: XMYY-2025KYSB353

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Preoperative risk communication in patients scheduled for elective cranial neurosurgery for intracranial space-occupying lesions

Interventions
Before randomization, all 67 patients and/or LARs discussed their conditions with the neurosurgeons and signed the relevant informed consent forms. During this process, 5 patients opted out. Ultimately, the 62 communication participants who engaged in the communication all completed the State-Trait Anxiety Inventory (STAI-Form Y-Chinese Version, https://scales.arabpsychology.com/Ch/state-trait-anxiety-inventory-stai-form-y-chinese-version/), which was used to evaluate the participants' state anxiety (State Anxiety Inventory, STAI Y-1) and trait anxiety (Trait Anxiety Inventory, STAI Y-2), with higher scores indicating higher levels of anxiety. To evaluate the comprehension abilities of the communication participants, the researchers assessed their cognitive function using the Montreal Cognitive Assessment (MOCA, Chinese 7.1-Beijing) (https://mocacognition.com). Randomization was then performed within three strata. In the experimental group (AR group), the communication participants wore the SeerLens® AR device when necessary, and the doctor superimposed the digital 3D model presented by the AR device onto the patient's real head, showing the corresponding spatial structures based on the patient’s actual lesion location and explaining them to the communication participant. In the control group (physical model group), the doctor provided explanations to the communication participant with the assistance of a physical anatomical model.

After the communication, the doctor will perform another evaluation of the communication recipient. This evaluation includes: (1) A medical knowledge comprehension questionnaire: (i) A subjective understanding rating scale (Cronbach's α=0.88) (Supplementary file 2) to assess subjective comprehension. (ii) An objective comprehension assessment (Supplementary file 3): Evaluated using directed multiple-choice questions, which cover the patient’s current diagnosis, initial treatment plan, tumor location, surgical method, intraoperative adverse events, and complications. (2) Anxiety assessment (STAI-Form Y Chinese Version: STAI Y-1 and STAI Y-2). (3) A self-developed communication satisfaction rating scale (Cronbach's α=0.86) (Supplementary file 4).

The entire communication process is timed by the physician conducting the conversation. The entire communication process is video recorded for subsequent independent researchers to use the SEGUE scale (Chinese version, https://m.medsci.cn/scale/show.do?id=50cc362ee3)to independently assess the communication skills of the physician.

Intervention Type

Supplement

Primary outcome(s)
1. The potential impact of using a head-mounted AR device for risk communication on recipients' understanding of medical information such as the patient's condition and surgical strategy measured using a medical knowledge comprehension questionnaire: (i) a subjective understanding rating scale (Cronbach's α=0.88) to assess subjective comprehension; (ii) an objective comprehension assessment: evaluated using directed multiple-choice questions, which cover the patient's current diagnosis, initial treatment plan, tumor location, surgical method, intraoperative adverse events, and complications, at before and after doctor-patient communication

Key secondary outcome(s))
1. Overall satisfaction of the communication recipients; changes in recipients' anxiety levels before and after the risk communication; the time spent on communication; and the communicating physician's communication skills (assessed under standardized control), measured using anxiety assessment (STAI-Form Y Chinese Version: STAI Y-1 and STAI Y-2); a self-developed communication satisfaction rating scale (Cronbach's α=0.86), at before and after doctor-patient communication

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Neurosurgery patients eligible for elective or semi-elective surgery with a feasible standard surgical approach.
2. High-quality Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Digital Imaging and Communications in Medicine (DICOM) format imaging data from the hospital within 3 days before surgery. If needed, updated imaging must be completed before communication.
3. Eligibility of the communication recipient: The recipient has no visual or auditory impairments, no mental illness, and no cognitive disorders. (i) The patient has the ability to provide informed consent and communicate; (ii) or the patient's LAR is the primary participant in communication and decision-making (when the patient lacks capacity or has delegated authority).
4. Age and language of the communication recipient: Aged between 18 and 70 years; able to complete questionnaires and tests in Chinese (Mandarin); no gender restriction.
5. Cooperation and compliance: Agree to randomization, complete on-site evaluation, and follow-up before discharge; willing to wear AR display devices when necessary (AR group).
6. Ethical consent: Sign the informed consent related to the study (by the patient or LARs), and allow desensitized use of three-dimensional imaging data for demonstration.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Clinical process-related:
1.1. Emergency surgery patients who cannot be given 24 hours or more for preoperative assessment and communication.
1.2. Patients with severe cognitive or consciousness disorders who are unable to complete the assessment and lack a qualified LARs participant (e.g., persistent delirium, severe aphasia, GCS score ≤ 12: E4+V3+M5 or E2+V5+M5).
1.3. Difficulty cooperating with questionnaires and tests: reading/writing disabilities, inability to complete the tests, and inability to provide equivalent alternative methods (oral expression+researcher recording).
1.4. Recently participated in similar intervention studies or communication-related intervention trials in the past 3 months that may affect primary outcomes (e.g., understanding/decision conflict).
2. Contraindications or high risks related to head-mounted AR devices
2.1. History of photosensitive epilepsy or epilepsy clearly induced by visual stimuli.
2.2. Vestibular dysfunction (frequent dizziness attacks in the last 3 months or daily medication to control symptoms).
2.3. Patients with severe migraines who are highly sensitive to bright light/dynamic images and have frequent episodes recently.
2.4. Severe visual impairments or eye diseases affecting AR device usage (e.g., corrected vision ≤ 0.1, poor control of diplopia, post-ocular surgery recovery period).
2.5. Severe hearing impairments and no equivalent alternative communication methods available on-site (e.g., subtitles/hearing aids).
2.6. Limitations on wearing and positioning: Those unable to safely wear head-mounted AR devices due to external head fixation (e.g., Halo brace), large head dressings, or cervical fixation devices (e.g., neck collar).
2.7. Clear history of adverse reactions to AR devices that led to discontinuation (e.g., severe nausea, balance issues) and the subject’s refusal to attempt again.
3. Others:
3.1. Communication or ethical risks deemed inappropriate for inclusion (e.g., family conflict affecting voluntariness).
3.2. Legal restrictions or special populations requiring extra approval that have not been granted (e.g., populations under compulsory supervision).

Date of first enrolment
06/01/2025

Date of final enrolment
08/09/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
First Affiliated Hospital of Xiamen University

ROR
https://ror.org/0006swh35

Funder(s)

Funder type

Funder Name
First Affiliated Hospital of Xiamen University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/04/2026	20/04/2026	Yes	No