

Official title:

Impact of Personalized Preoperative Psychological Intervention on
Perioperative Anxiety and Depression in Patients Undergoing Oocyte
Retrieval: A Randomised Controlled Study

NCT number: NCT06475690

Document date: 2024-07-02

Study design and Statistical analysis

This is a prospective, single-blind, randomized controlled trial conducted at the Reproductive Medicine Center of the First Affiliated Hospital of Chongqing Medical University from September 8, 2024 to June 24, 2025 (registration number: NCT06475690). It was approved by the ethics committee and written informed consent was obtained from all participants.

Study Population: 179 valid female patients scheduled for oocyte retrieval under general anesthesia were included, aged 20 – 44 years and able to complete questionnaires via smartphone. Exclusion criteria included psychiatric disorders, morbid obesity, severe cardiovascular/endocrine diseases, history of serious anesthesia-related adverse events, etc.

Interventions: Participants were randomized 1:1 into two groups:

Active Communication Group (AC Group): Received individualized pre-anesthesia communication from an anesthesiologist, addressing concerns, providing tailored information, and offering emotional support.

Control Group (CON Group): Received routine pre-anesthesia communication, which only informed patients of potential risks and standard management protocols.

Measures & Time Points:

APAIS: Assessed preoperative anxiety and information needs at 24 h before surgery and 1 h preoperatively.

GAD-7, PHQ-9, HADS: Evaluated anxiety and depressive symptoms at 24 h preoperatively and 24 – 48 h postoperatively.

Anesthesia & Perioperative Care: Standardized intravenous anesthesia with propofol and remifentanyl was used, with intraoperative monitoring of BIS and vital signs. Postoperatively, pain and nausea/vomiting were managed in the PACU according to VAS scores and clinical guidelines.

Sample Size & Statistics: The required sample size was 170, and 180 participants were enrolled (179 valid) to account for 5% loss to follow-up. Statistical analyses were performed using SPSS 26.0: baseline comparisons used t-test/Mann-Whitney U

test/ χ^2 test; the primary outcome was analyzed by ANCOVA, with a two-sided α of 0.05 considered statistically significant.