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Arachidonic acid supplementation for cognitive improvement in schizophrenia: a randomized controlled trial

Submission date
25/07/2025

Recruitment status
No longer recruiting

Registration date
28/07/2025

Overall study status
Completed

Last Edited
25/07/2025

Condition category
Mental and Behavioural Disorders

[X] 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
Cognitive impairment associated with schizophrenia (CIAS) encompasses deficits in working memory, learning ability, and other core cognitive functions. Current antipsychotic treatments show limited efficacy in improving these symptoms. Arachidonic acid (AA), a key polyunsaturated fatty acid, plays crucial roles in neuronal membrane integrity and synaptic plasticity. Emerging evidence suggests AA deficiency may contribute to schizophrenia pathogenesis and cognitive dysfunction.
This randomized controlled trial aims to:
1. Investigate whether AA supplementation (350 mg/day) improves cognitive function in schizophrenia patients
2. Explore molecular mechanisms linking AA metabolism to cognitive enhancement

Who can participate?
Patients with SZ registered at the Suzhou Guangji Hospital, Jiangsu Province, China.

What does the study involve?
Participants will be randomly assigned (1:1) to AA group (350 mg AA daily + standard treatment) or Placebo group (Matching placebo + standard treatment)
Duration: 6 weeks
Assessments: Cognitive function (CANTAB battery) at baseline, 3 weeks, and 6 weeks; Blood samples for AA levels at baseline and endpoint; Safety monitoring throughout

What are the possible benefits and risks of participating?
Potential benefits:
• Improved cognitive performance
• Comprehensive health monitoring
• Free cognitive assessments
Potential risks:
• Psychological stress during testing
• Placebo group may not experience cognitive improvement

Where is the study run from?
1. Shanghai Jiao Tong University Bio-X Institute (China)
2. Suzhou Guangji Hospital (collaborating site) (China)

When is the study starting and how long is it expected to run for?
June 2025 to October 2025

Who is funding the study?
National Natural Science Foundation of China
Shanghai Jiao Tong University (China)

Who is the main contact?
Contact Principal Investigator: Chunling Wan, PhD Email: clwan@sjtu.edu.cn

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A randomized, double-blind, placebo-controlled trial of arachidonic acid (AA) supplementation for cognitive impairment in schizophrenia

Study objectives
To evaluate whether 6-week arachidonic acid (AA) supplementation improves cognitive function in schizophrenia patients, as measured by CANTAB neuropsychological tests.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/06/2025, Shanghai Jiao Tong University (800 Dongchuan Road, Minhang District, Shanghai, 20030, China; -; IRB.HRP@sjtu.edu.cn), ref: B20250551I

Study design
Single-center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia

Interventions

This randomized, double-blind, placebo-controlled trial will compare arachidonic acid (AA) supplementation versus placebo in schizophrenia patients. Eligible participants will be randomly allocated 1:1 to either:
1. AA group: Oral administration of 350 mg AA once daily after breakfast for 6 weeks, alongside standard antipsychotic treatment.
2. Placebo group: Identical-appearing formulation containing fatty acids without AA, administered under the same regimen.
Randomization will be performed using computer-generated sequences with concealed allocation. All participants will maintain their prescribed antipsychotics without dosage adjustments during the trial. Cognitive function assessed using CANTAB and blood AA levels will be assessed at baseline, 3 weeks, and 6 weeks. Adherence will be monitored through medication count and patient diaries

Intervention Type
Supplement

Primary outcome(s)
Cognitive function will be measured using the Cambridge Neuropsychological Test Automated Battery® (CANTAB®) system at baseline, week 3, and 6.

Key secondary outcome(s))
RBC's fatty acids will be measured using gas chromatography-mass spectrometry at baseline and week 6.

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of schizophrenia according to ICD-10 criteria
2. Willingness to participate, with signed informed consent from the patient or their legal guardian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1.Patients should not have a history of other mental disorders, neurological disorders, serious physical diseases, traumatic brain injury, substance abuse, or dependence
2. Enrollment in another clinical trial within 4 weeks prior to screening
3. Pregnancy, lactation, or plans to conceive during the study

Date of first enrolment
01/08/2025

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
China

Study participating centre
Suzhou Guangji Hospital
No. 11 Guangqian Street, Xiangcheng District
Suzhou
China
215131

Sponsor information

Organisation
Shanghai Jiao Tong University

ROR
https://ror.org/0220qvk04

Funder(s)

Funder type
Government

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
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication