

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

Submission date 25/07/2025	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/07/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/07/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

Prof Chunling Wan

ORCID ID

<https://orcid.org/0000-0002-0372-0041>

Contact details

No. 1954, Huashan Road
Shanghai
China
200030
+ 86 21 62833148
clwan@sjtu.edu.cn

Type(s)

Scientific, Principal investigator

Contact name

Dr Xiaowen Hu

Contact details

No. 1954, Huashan Road
Shanghai
China
200030
+ 86 21 62833148
xiaowen@sjtu.edu.cn

Type(s)

Public, Scientific

Contact name

Dr Yan Gao

Contact details

No. 1954, Huashan Road
Shanghai
China
200030
+86 21 62833148
Gao_Yan@sjtu.edu.cn

Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

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 Wěiyuánhùi, , 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes