

Arachidonic acid supplementation to improve cognitive impairment of schizophrenia

Submission date 04/07/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/08/2024	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) is characterized by a broad pattern of cognitive deficits ranging from attention and working memory to social cognition and language. Currently, the main antipsychotic maintenance treatment has a limited substantial effect on improving cognitive performance and barely makes a full recovery in socialization. In the brain, arachidonic acid (AA) is mainly esterified into lipids, serving as cellular membrane components for the dynamic morphological change of neuron cells and signaling molecules during neurotransmission.

Given the multi-involvements of AA in brain development and neuronal activities, this study aims to investigate the efficacy of AA supplementation in improving cognitive function among SZ patients and to elucidate the underlying mechanisms, thereby offering new perspectives and strategies for the treatment of cognitive impairments.

Who can participate?

Patients with SZ and healthy participants registered at the Suzhou Guangji Hospital, Jiangsu Province, China.

What does the study involve?

Patients and healthy participants are randomly assigned to powdered FA supplements containing AA or the AA-free placebo once daily for nutraceutical supplementation. The niacin skin flushing response, and cognition performance are assessed by trained psychiatrists at the beginning, midpoint, and endpoint. Blood samples are taken at the beginning and endpoint.

What are the possible benefits and risks of participating?

Participants who receive the AA may benefit from improved cognitive performance. There are no known risks involved with participating.

Where is the study run from?

1. Shanghai Jiao Tong University (China)
2. Suzhou Guangji Hospital, Jiangsu Province (China)

When is the study starting and how long is it expected to run for?
November 2020 to December 2024

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

Who is the main contact?
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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information**Scientific Title**

Exploring the impact and underlying mechanisms of arachidonic acid supplementation on cognitive impairment in schizophrenia: a double-blinded, placebo-controlled, randomized study

Study objectives

This study aims to evaluate the therapeutic effects and underlying mechanisms of arachidonic acid supplementation on cognitive improvement.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/11/2020, Research Ethics Committee of Bio-X Institutes, Shanghai Jiao Tong University (No. 1954 Huashan Road, Xuhui District, Shanghai City, Shanghai, 200030, China; +86 21-62932151; bio-x@sjtu.edu.cn), ref: No. M202006

Study design

Single-center interventional double-blinded randomized placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

This was designed for a double-blinded, placebo-controlled, randomized clinical trial (RCT) of oral arachidonic acid (AA) supplementation to identify whether the adjunctive intervention can improve cognitive performance in schizophrenia and healthy controls.

Patients were recruited and randomly assigned to powdered FA supplements containing 338 mg AA or the AA-free placebo once daily for a six-week adjunctive intervention.

The AA supplements and the placebo were identical in powder particle size, color, volume, and packaging. The diet of inpatients remains consistent during their hospital stay.

Healthy volunteers were recruited to FA supplements containing 1400 mg AA for an eight-week intervention and four-week wash-out period.

Stratified randomisation based on patient gender, age, height, weight, and cognitive performance measured by CANTAB system. We are utilizing an online tool for this process, which ensures that each stratum is randomly assigned participants.

Intervention Type

Supplement

Primary outcome measure

Cognitive function was measured using the Cambridge Neuropsychological Test Automated Battery® (CANTAB®) system at baseline, week 3, and 6

Secondary outcome measures

1. RBC's lipids and fatty acids were measured using gas chromatography-mass spectrometry at baseline and week 6
2. Mitochondria lipids measured using ultrahigh-performance liquid chromatography quadrupole orbitrap mass spectrometry at baseline and endpoint
3. RNA sequencing of white blood cells was conducted at baseline and endpoint
4. Niacin skin flushing response test using 6 concentrations (triple gradient dilution from 60 mM) of niacin dropped onto the skin at baseline, week 3, and 6

Overall study start date

02/11/2020

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. Patients of SZ were diagnosed according to the International Classification of Diseases 10th edition (ICD-10)
2. The patient's family members or legal guardians fully understood the content of this study and signed informed consent

Participant type(s)

Healthy volunteer, Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

80 = 40 in AA group and 40 in AA-free placebo group

Total final enrolment

62

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. Healthy controls should not have any current or previous psychiatric history or family history, as assessed by the Mini-International Neuropsychiatric Interview (M.I.N.I.)

Date of first enrolment

08/11/2020

Date of final enrolment

22/02/2021

Locations

Countries of recruitment

China

Study participating centre**Suzhou Guangji Hospital**

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Jiangsu Province
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215131

Sponsor information

Organisation

National Natural Science Foundation of China

Sponsor details

No. 83 Shuangqing Road, Haidian District
Beijing
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Sponsor type

Government

Website

https://www.nsfc.gov.cn/english/site_1/index.html

ROR

<https://ror.org/01h0zpd94>

Organisation

Shanghai Jiao Tong University

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Sponsor type

University/education

Website

<https://en.sjtu.edu.cn/>

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

Funder Name

Shanghai Jiao Tong University

Alternative Name(s)

, , Nanyang Public School, Nan Yang College of Chiao Tung, National Chiao Tung University, Jiao Tong University, SJTU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

China

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2025

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