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Arachidonic acid supplementation to improve cognitive impairment of schizophrenia

Submission date
04/07/2024

Recruitment status
No longer recruiting

Registration date
05/07/2024

Overall study status
Completed

Last Edited
30/12/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[X] 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) 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?
1. Prof. Chunling Wan, clwan@sjtu.edu.cn
1. Dr. Xiaowen Hu, xiaowen@sjtu.edu.cn
2. Yan Gao, Gao_Yan@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)
Public, Scientific

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
Miss Yan Gao

ORCID ID
https://orcid.org/0000-0001-6905-0143

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
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

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
No. 11 Guangqian Street, Xiangcheng District, Suzhou City
Jiangsu Province
China
215131

Sponsor information

Organisation
National Natural Science Foundation of China

ROR
https://ror.org/01h0zpd94

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

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

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?
Statistical Analysis Plan			30/12/2025	No	No