ISRCTN10306750 https://doi.org/10.1186/ISRCTN10306750

Study on schizophrenia patients responsive to fish oil supplementation therapy

Submission date
19/12/2023

Recruitment status
No longer recruiting

Registration date
29/12/2023

Overall study status
Completed

Last Edited
02/12/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
Schizophrenia is a complex disorder that presents long-term challenges such as a lack of objective diagnostic markers and complex and varying clinical symptoms. The blunted niacin skin flushing response is commonly observed in patients with schizophrenia and is considered one of the objective diagnostic markers for the disorder. It is closely related to the membrane lipid disorder hypothesis of schizophrenia, which suggests that schizophrenia subgroups selected based on blunted niacin response are believed to be caused by membrane lipid disorders. Factors leading to membrane lipid disorders in the body include lipid peroxidation caused by oxidative stress and inflammatory responses. Fish oil is a common antioxidant and anti-inflammatory supplement, composed mainly of n-3 polyunsaturated fatty acids, which are important components of membrane lipids. In this study, we randomly assigned participants to groups and added fish oil supplementation to the conventional treatment in the experimental group. The aim was to identify the schizophrenia population that responds well to this supplementary treatment of fish oil, with the expectation of providing guiding suggestions for clinical treatment.

Who can participate?
Patients aged between 18 and 65 years with schizophrenia who are registered at Renmin Hospital of Wuhan University, and eligible healthy volunteers

What does the study involve?
The patients were randomly recruited in the hospital outpatient department and were divided into into a control group and an experimental group. The control group received conventional treatment, while the experimental group was given additional fish oil supplementation.The supplemental dose of fish oil (Puritan’s Pride OMEGA-3 Fish Oil, USA) is 1800-2700 mg per day. Niacin response were administered to all subjects before treatment (baseline) by trained psychiatrists, and all patients were assessed with the Positive and Negative Syndrome Scale (PANSS). At follow-up, niacin response and PANSS scales were assessed in fish oil supplementation patients.

What are the possible benefits and risks of participating?
All participants have access to a clinical evaluation by the professional psychiatrists, which is free

of charge. And participants who receive the PUFA may benefit from a reduction of their psychiatric symptoms. There are no known risks involved with participating.

Where is the study run from?
Renmin Hospital of Wuhan University (China)

When is the study starting and how long is it expected to run for?
January 2019 to December 2023

Who is funding the study?
National Natural Science Foundation of China

Who is the main contact?
1. Shijing Wang, wdrmiit@163.com
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Study on efficacy evaluation of fish oil supplementation therapy for schizophrenia based on niacin skin flushing responses

Study objectives

Current study objectives as of 02/12/2025:

Blunted niacin response is widely shown in patients with schizophrenia, which has become an objective auxiliary diagnostic marker for schizophrenia and is closely related to the pathological hypothesis of abnormal membrane phospholipids in schizophrenia. The main component of fish oil is n-3 polyunsaturated fatty acid, which plays an important physiological role in regulating membrane phospholipids. This study aims to identify schizophrenia patients with impaired nicotinic acid response and provide fish oil supplementation as a targeted intervention, ultimately identifying the population that responds to fish oil supplementation, reducing trial-and-error costs, and improving treatment efficiency.

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Previous study objectives:

Blunted niacin response is widely shown in patients with schizophrenia, which has become an objective auxiliary diagnostic marker for schizophrenia and is closely related to the pathological hypothesis of abnormal membrane phospholipids in schizophrenia. The main component of fish oil is n-3 polyunsaturated fatty acid, which plays an important physiological role in regulating membrane phospholipids. This study aims to identify schizophrenia patients with impaired niacin response and administer fish oil supplementation as a targeted intervention, ultimately shedding light on the potential of niacin flush response as a guide for clinical schizophrenia treatment and prognostic indicators.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/05/2019, Ethics Committee of Bio-X Institutes at Shanghai Jiao Tong University (Shanghai, Huashan Road, Shanghai, 200030, China; +86 (0)15921495069; wangdandan26@126.com), ref: ML2019041

Study design
Interventional open-label randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current interventions as of 02/12/2025:

Patients with mental disorders were randomly allocated to the experimental group and the control group. The control group received routine treatment, whereas the experimental group received adjuvant fish oil supplementation in addition to routine treatment, with a total treatment course of 21 days. The method of randomisation is according to a computer-

generated random sequence using block randomisation with random block sizes. The randomisation is performed by the independent statistician. Patients are enrolled and assigned sequentially to adjuvant interventions by the physician. The allocation sequence is not available to any member of the research team until the databases had been completed and locked.

The supplemental dose of fish oil (Puritan's Pride OMEGA-3 Fish Oil, USA) is 1800-2700 mg per day.

All patients were assessed with the Positive and Negative Syndrome Scale (PANSS). At follow-up, niacin response and PANSS scales were assessed in fish oil supplementation patients.

Previous interventions:

Recruited patients are tested for niacin skin flushing responses and divided into blunted and normal niacin response groups according to their niacin skin flushing responses. Subsequently, patients with blunted niacin responses are randomly were randomly assigned to receive fish oil supplementation for 3 months. Those not randomly assigned were not given fish oil supplementation. The method of randomisation is according to a computer-generated random sequence using block randomisation with random block sizes. The randomisation is performed by the independent statistician. Patients are enrolled and assigned sequentially to adjuvant interventions by the physician. The allocation sequence is not available to any member of the research team until the databases had been completed and locked.

The supplemental dose of fish oil (Puritan's Pride OMEGA-3 Fish Oil, USA) is 1800-2700 mg per day.

Niacin response and Brief Assessment of Cognition in Schizophrenia (BACS) were administered to all subjects before treatment (baseline) by trained psychiatrists, and all patients were assessed with the Positive and Negative Syndrome Scale (PANSS). At follow-up, niacin response, BACS and PANSS scales were assessed in fish oil supplementation patients.

Intervention Type
Supplement

Primary outcome(s)
Psychotic symptoms measured using the Positive and Negative Syndrome Scale were measured at baseline and month 3

Key secondary outcome(s))
Current key secondary outcome(s) as of 02/12/2025:

1. Niacin skin flushing response were measured at baseline and month 3

Previous key secondary outcome(s):

1. Niacin skin flushing response were measured at baseline and month 3
2. Cognition measured using the Brief Assessment of Cognition in Schizophrenia were measured at baseline and month 3

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients with schizophrenia diagnosed according to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria
2. Age between 18 and 65 years
3. Commitment to comply with the study procedures and cooperate with the implementation of the entire research process

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
132

Key exclusion criteria
1. Severe neurological diseases or traumatic brain injury
2. Substance dependence
3. Administration of nonsteroidal or steroidal anti-inflammatory drugs within 2 weeks
4. Having a history of severe allergies, currently suffering from skin diseases or immune system diseases
5. Pregnancy

Date of first enrolment
01/06/2019

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
China

Study participating centre
Renmin Hospital of Wuhan University
238 Jiefang Road
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China
430000

Sponsor information

Organisation
Renmin Hospital of Wuhan University

ROR
https://ror.org/03ekhbz91

Funder(s)

Funder type
Research organisation

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 during and/or analysed during the current study will be available upon request from Shijing Wang (wdrmiit@163.com). The data will be available beginning 3 months and ending 5
years following article publication. It can be shared with researchers who provide a methodologically sound proposal to achieve the aims in the approved proposal. To gain access, data requesters will need to sign a data access agreement. Consent from participants was obtained. Data will be de-identified by removing personally identifiable information.

IPD sharing plan summary

Available on request

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