

Bifidobacterium with high-frequency transcranial stimulation adolescent depression

Submission date 14/03/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/03/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/10/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

To explore the efficacy and safety of Bifidobacterium combined with high-frequency transcranial magnetic stimulation in the treatment of adolescent depression.

Who can participate?

Adolescents aged 13-18 years old with depression who were admitted to the participating hospital

What does the study involve?

Participants were randomly divided into two groups to compare treatment effects after eight weeks.

What are the possible benefits and risks of participating?

Bifidobacterium combined with high-frequency transcranial magnetic stimulation is effective in the treatment of adolescent depression with a favorable safety profile.

Where is the study run from?

Wenzhou Seventh People's Hospital, China

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

January 2022 to October 2022

Who is funding the study?

Wenzhou Seventh People's Hospital, China

Who is the main contact?

Cong-Cong Chen, chen33congc9ong3@yeah.net

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Cong-Cong Chen

Contact details

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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**

Efficacy and safety of bifidobacterium combined with high-frequency transcranial magnetic stimulation in the treatment of adolescent depression: a preliminary randomized controlled trial

Study objectives

Bifidobacterium combined with high-frequency transcranial magnetic stimulation is effective in the treatment of adolescent depression

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 26/08/2021, Wenzhou Seventh People's Hospital (Room 218, 2nd floor, outpatient building, 158 Xueshiqian, Panqiao street, Ouhai District, Wenzhou City, Zhejiang Province, 325000, China; +86 0577-89870004; wqyllwyh@126.com), ref: EC-20210826-03

Study design

Single-center intervention single-blind randomized-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bifidobacterium combined with high-frequency transcranial magnetic stimulation in the treatment of adolescent depression

Interventions

A total of 100 patients were selected, and divided into the experimental group(n=50) and the control group(n=50) using a random number table. Patients in the experimental group were treated with Bifidobacterium and high-frequency transcranial magnetic stimulation (rTMS), and those in the control group were treated with oral escitalopram oxalate. After 8 weeks of treatment, the Hamilton Rating Scale for Depression (HAMD-24) score, serum inflammatory factors, neuroendocrine indicators and miRNAs were determined in both groups. The random double-blind principle was strictly followed during the whole process of the study.

Intervention Type

Mixed

Primary outcome(s)

Depression symptoms measured using the Hamilton Rating Scale for Depression (HAMD-24) score before and after treatment

Key secondary outcome(s)

The following secondary outcome measures are assessed before and after treatment:

1. The levels of serum inflammatory factors and neuroendocrine indicators: serum tumor necrosis factor- α (TNF- α), interleukin-1 β (IL-1 β), IL-6, dopamine(DA), 5-hydroxytryptamine(5-HT) and cortisol(COR) were measured by ELISA using an automatic biochemical analyzer (Dxc800, Beckman, USA).
2. The relative expression levels of serum miR-16 and miR-195 were measured using PCR
3. Remission rate measured using HAMD scores (difference in scores before and after treatment /score before treatment \times 100%)
4. The incidence rate of adverse reactions measured using events reporting and calculated by dividing the number of patients with adverse reactions by the total number of patients

Completion date

31/10/2022

Eligibility

Key inclusion criteria

1. Aged 13-18 years old
2. Met the diagnostic criteria for depression in the International Classification of Disease-10 (ICD-10)
3. With a total score of the Hamilton Rating Scale for Depression (HAMD-24) ≥ 20 in the initial assessment
4. Who were right-handed

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

13 years

Upper age limit

18 years

Sex

All

Total final enrolment

100

Key exclusion criteria

1. With a definite diagnosis of other mental disorders in the past
2. With a past or current history of manic episodes
3. With a past or current history of severe physical diseases
4. Who used antidepressants, mood stabilizers, steroids, anti-inflammatory drugs, antibiotics, and immunomodulators in the past 1 month
5. Who used lactic acid bacteria products for ≥ 7 days in the past 1 month
6. With a history of alcohol or psychoactive substance abuse within the last 3 months
7. With contraindications for RTMS, including but not limited to intracranial metal foreign bodies, cardiac pacemakers, and ear hearing aids
8. Complicated with organic brain diseases, epileptic diseases, and severe physical diseases

Date of first enrolment

01/03/2022

Date of final enrolment

31/10/2022

Locations**Countries of recruitment**

China

Study participating centre

Wenzhou Seventh People's Hospital

552 Xishan East Road, Ouhai District

Wenzhou, Zhejiang

China

325000

Sponsor information

Organisation

Wenzhou Seventh People's Hospital

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Wenzhou Seventh People's Hospital

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 Cong-Cong Chen (chen33congc9ong3@yeah.net).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/10/2025	20/10/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes