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Bifidobacterium with high-frequency transcranial stimulation adolescent depression

Submission date	Recruitment status	[ ] Prospectively registered
14/03/2025	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/03/2025	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/03/2025	Mental and Behavioural Disorders	[X] Record updated in last year

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
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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
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 buidling, 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

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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-1β (IL-1β), 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 × 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

Overall study start date
01/01/2022

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

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
116

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
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Sponsor information

Organisation
Wenzhou Seventh People's Hospital

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wenzhou Seventh People's Hospital

Results and Publications

Publication and dissemination plan
Planned for publication in a peer-reviewed journal

Intention to publish date
01/04/2025

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