Study on the Molecular Mechanism of Berberine to Improve Type 2 Diabetes Mellitus Complicated With Depression (SBDD)

Informed Consent Form

NCT06979440

18/5/2025

Informed Consent Form

Dear Sir/Madam,

We sincerely invite you to participate in the research project titled "Molecular Mechanisms of Berberine in Modulating Gut Microbial Metabolite 5-AVAB to Improve Type 2 Diabetes with Comorbid Depression (T2DD)." This study is funded and approved by the National Natural Science Foundation of China and has been reviewed and authorized by the Ethics Committee of Affiliated Hospital of Nantong University.

Your participation is entirely voluntary. If you choose not to participate, it will not affect your medical treatment or rights. You may also withdraw from the study at any time.

This Informed Consent Form is provided in duplicate. If you agree to participate, you may consult your research physician regarding any questions. After full comprehension, you and your research physician will both sign this form, and you will retain one copy.

1. Why is this research being conducted?

Background:

Type 2 diabetes with comorbid depression (T2DD) has a high prevalence, chronic course, and frequent relapses. Our preliminary experiments suggest that 5-AVAB, a gut microbial metabolite, may serve as a novel biomarker for T2DD. However, no prior research has explored this mechanism, warranting further investigation.

Research Purpose: To collect fecal and serum samples from patients with type 2 diabetes (T2D) and type 2 diabetes with comorbid depression (T2DD), for quantitative analysis of 5-AVAB concentrations and in vitro cultivation and sequencing studies of intestinal microbiota.

2. Eligibility Criteria and Participant Enrollment

Inclusion/Exclusion Criteria:a. Age 18–65 years; b. Control group: Diagnosed with Type 2 Diabetes Mellitus (T2DM) without a history of psychiatric disorders; T2DD group: Diagnosed with T2DM and comorbid depression (depression must meet DSM-5 diagnostic criteria); c. No use of antibiotics, prebiotics, probiotics, or enteral

nutrition medications within 3 months prior to enrollment, nor during the study period.

This study will enroll individuals with Type 2 Diabetes Mellitus (T2DM) and Type 2 Diabetes Mellitus with Comorbid Depression (T2DD). The research will be conducted at Affiliated Hospital of Nantong University over a 3-year period, with an estimated enrollment of 40 participants.

3. Research Process

This study is a non-interventional study, and participation will not affect your routine treatment. If you agree to participate, we will collect 5 mL of blood and 5 g of fresh stool once during your regular medical visits. We will also collect relevant medical records from your clinical treatment for analysis and conduct detailed discussions with you or your family to gather disease-related information, including the onset process, family history, previous medical visits, and past examination results. Your samples/medical records will only be used for this study.

If you agree to participate, each participant will be assigned a unique identification number, and medical records will be archived for the study.

4. Risks and Benefits of the Study

This study involves no additional interventions. Therefore, participation is unlikely to cause harm to your physical health, psychological state, or social relationships beyond routine clinical care, nor will it negatively impact your disease diagnosis or treatment.

Your participation may help clarify the diagnosis of your condition, provide necessary recommendations for your current treatment, or offer useful information for future treatment and follow-up. Alternatively, you may receive no direct benefit from participating. However, this research may provide critical theoretical foundations and new therapeutic targets for treating Type 2 Diabetes with Comorbid Depression (T2DD), benefiting the diagnosis and treatment of diabetes and depression-related diseases. We sincerely thank you for contributing to medical research.

5. Study-Related Costs, Compensation, and Liability

This is a non-interventional study, and it imposes no financial burden beyond standard clinical care. Fasting blood glucose tests, psychological assessments for

depression, and other study-related examinations are provided free of charge. While no compensation will be offered for participation, your involvement will significantly advance therapeutic research on type 2 diabetes with comorbid depression. We sincerely appreciate your contribution to medical science.

6. Privacy Protection and Data Security

Your personal privacy will be rigorously protected. All provided data will be managed confidentially and stored on password-encrypted hard drives within researchers' dedicated computers, retained for up to 3 years post-study completion. Access is restricted to authorized research personnel; however, government authorities, institutional regulatory bodies, or ethics review boards may review the data as legally required.

Research findings may be published in academic journals, but no personally identifiable information will be disclosed. Your personal details and questionnaire responses will not be used for unrelated studies unless de-identified data are applied to future scientific investigations.

7. Rights and Obligations

Participation in this study is entirely voluntary. You may refuse to participate or have the right to withdraw at any stage without reason, and you will not face penalties, discrimination, or retaliation. Your medical treatment and rights will not be affected. If any new, significant information that might influence your willingness to continue the study arises during the research period, your assigned research physician will immediately inform you.

8. Contact Information

If you have questions or require information related to the study, please contact us at any time. Researcher contact: Zhengwei Zhang, 15701539317. For inquiries regarding participant rights, contact the Ethics Committee: 0513-85052390.

Appendix: Informed Consent Form · Consent Signatory Page

If you fully comprehend the nature of this research project and consent to participate, you shall sign this informed consent form in duplicate, with one copy retained by the researcher and the other by the participant/legal guardian/authorized representative.

Signatory (Participant or Legal Guardian):

Declaration of Consent:

1. I confirm that I have read and understood this informed consent form. Potential issues arising during the research, as well as corresponding resolutions, have been explained to me, and I have had the opportunity to raise questions.
2. I acknowledge that participation in this study is entirely voluntary, and refusal to participate will not compromise any of my entitlements or benefits.
3. I am informed that research physicians, health administrative authorities, and the Ethics Committee reserve the right to review research records and medical data. I consent to the direct access of my research records by the aforementioned parties, under the assurance of confidentiality.
4. I agree to participate in this study.

Participant Signature: _____ Date: _____

Contact (Mobile): _____

(If the participant lacks or has insufficient capacity to provide informed consent, add or substitute the following section):

Legal Guardian Signature: _____ Date: _____

Contact (Mobile): _____

Impartial Witness Signature: _____ Date: _____

Reason for Witness Attestation: _____

Contact (Mobile): _____

Researcher Declaration: I confirm that I have explained and discussed the nature, purpose, requirements, and potential risks of this study with the participant, explored alternative treatment options, and ensured that a copy of this informed consent form has been provided to the participant for retention.

Researcher Signature: _____ Date: _____

Contact (Mobile): _____