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A Randomized Controlled Trial of Branched-Chain Amino Acid Supplementation for Preventing Myopia Progression

Informed Consent Form

Version No.: 04

Version Date: July 1, 2026

This version incorporates minor corrections and clarifications and reflects the informed consent form used since study initiation.

Study Title

A Randomized Controlled Trial of Branched-Chain Amino Acid Supplementation for Preventing Myopia Progression

Principal Investigator: Weina Liu

Study Center Address: School of Public Health, Southeast University

Dear Sir/Madam,

You are invited to participate in the research study entitled **A Randomized Controlled Trial of Branched-Chain Amino Acid Supplementation for Preventing Myopia Progression**, funded by the National Natural Science Foundation of China. This study will be conducted at Zhongda Hospital Affiliated to Southeast University. It is estimated that 104 participants will voluntarily take part in the study. This study has been reviewed and approved by the Clinical Research Ethics Committee of Zhongda Hospital Affiliated to Southeast University. The ethics approval number is **2025ZDSYLL321-P01**.

Why is this study being conducted?

In recent years, myopia among university students in China has become increasingly serious and has emerged as a major public health challenge. Epidemiological investigations have shown that the prevalence of myopia among university students in Nanjing is as high as 86.8%, which is significantly higher than that in other age groups. Current major treatment approaches include behavioral interventions, drug therapy (such as atropine), and optical correction, but these methods have limitations such as poor adherence, strong side effects, and limited resources.

A key mechanism in myopia development involves remodeling of the scleral extracellular matrix (ECM) and the transdifferentiation of fibroblasts into myofibroblasts. Branched-chain amino acids (BCAAs) are aliphatic amino acids with branched carbon side chains and consist of three essential amino acids: leucine, isoleucine, and valine. They cannot be synthesized in the human body and must be obtained exogenously. They are key substrates for protein synthesis and, as essential amino acids, may exert anti-fibrotic effects by regulating ECM production. The BCAA capsules provided in this study are manufactured by Life Extension and are nutritional dietary supplements (not registered as a health food product), without an approval number or filing certificate (they belong to a category of cross-border e-commerce products that may be sold without a filing certificate). Previous animal experiments have shown that BCAA supplementation can delay myopia progression, but human data are lacking. Based on prior epidemiologic and pathophysiologic research, this study aims to evaluate the preventive effect of BCAA intervention on myopia progression in university students with myopia, and to develop a safe, low-cost, and highly adherent new nutritional intervention strategy to provide a scientific basis for nutritional prevention and control of myopia progression.

Who is suitable or unsuitable for participation?

Inclusion Criteria

1. Healthy university students aged 18-25 years;

2. Spherical equivalent refraction (for eyes without prior corneal refractive surgery): SE ≤ -0.50 D;

3. Corrected visual acuity ≥ 0.8;

4. Corneal curvature 40 D-46 D;

5. Good compliance and ability to cooperate with follow-up and examinations;

6. Willingness and ability to participate in this study and sign the informed consent form.

Exclusion Criteria

1. Strabismus, amblyopia, or other pathological ocular changes;

2. Systemic diseases affecting refractive development and allergic constitution, such as diabetes, metabolic syndrome, etc.;

3. Active eye disease or history of ophthalmic surgery;

4. Use of orthokeratology lenses or other myopia-control interventions within the past 6 months;

5. Use of BCAA-related supplements within the past 6 months, or serum BCAA levels outside the reference range;

6. Considered by the responsible physician to be unable to participate or unable to comply with the study requirements;

7. Abnormal liver or kidney function.

If I participate, what will I need to do?

If you meet the eligibility criteria for this study and decide to participate, you will be randomly assigned (like throwing dice) to receive one of the following treatment regimens. Before the study begins, you will also be asked to complete a questionnaire, which includes items on myopia status, lifestyle habits, family history of eye disease, and dietary survey:

- Wear regular single-vision myopia lenses or myopia-control lenses **and** take a placebo; or

- Wear regular single-vision myopia lenses or myopia-control lenses **and** take BCAA capsules.

You will take the nutritional supplement on time every day and return to the ophthalmology outpatient clinic of Zhongda Hospital Affiliated to Southeast University once every 3 month for follow-up. Follow-up procedures include vision examinations (spherical equivalent refraction, axial length, uncorrected visual acuity, intraocular pressure, fundus color photography, OCTA, visual function testing, etc.) and medical examinations (general physical examinations such as height, weight, blood pressure measurement, and other relevant health assessments).

Approximately 6 mL of venous blood will be collected from your forearm vein, mainly for testing serum BCAA levels as well as liver and kidney function, blood lipids, fasting blood glucose, and other indices. Blood collection will be performed twice, once at study initiation and once at the follow-up visit at the end of Month 6, with approximately 6 mL collected each time. Part of the collected blood sample will be tested in the Department of Laboratory Medicine of Zhongda Hospital Affiliated to Southeast University for liver and kidney function, blood lipids, and fasting blood glucose. Another part will be sent to the designated laboratory of this study for measurement of BCAA levels. These test data will be used only for scientific analysis and no individual result report will be provided to you.

After collection, the blood samples will be centrifuged immediately to separate serum. Serum samples will be anonymized using unique codes. The samples will be used only for scientific analyses related to this study and will not be used for any other purpose without your authorization. After the study is completed or the retention period expires, all samples will be safely destroyed in accordance with biomedical waste management regulations to ensure strict protection of participant privacy and sample security.

Each follow-up visit is expected to take approximately 1 hour. The purpose of follow-up is to assess the intervention effect and ensure continued attention to your health. Your participation in this study is expected to last about 6 months, including regular re-examinations. Among the above follow-up procedures and examinations, some tests (fundus color photography, OCTA, liver and kidney function, blood lipids, fasting blood glucose, and BCAA levels) are research-related procedures, meaning that you would not need to undergo these tests if you did not participate in this study.

What are the possible benefits of participating in this study?

Through regular follow-up, the research team will continuously monitor participants' visual health status and provide long-term consultation support. You may not receive any direct benefit from participating in this study. However, by exploring the relationship between BCAAs and myopia progression, this study

may provide safer and more effective new options for myopia prevention and control in people with myopia, and may reduce the risk of future high myopia and related complications.

What are the risks of participating in this study?

BCAAs are generally well tolerated, but in a small number of cases they may cause mild gastrointestinal discomfort, such as abdominal bloating, diarrhea, or nausea. The probability of these events is low, and most are transient and reversible reactions. Venous blood collection may cause pain and/or bruising. In rare cases, fainting during venipuncture or infection at the puncture site may occur, but these usually heal on their own. If you experience any discomfort or adverse reaction, please contact the study doctor promptly. In addition, the intervention may be ineffective, and it is possible that no preventive effect on myopia progression will be achieved.

Do I need to pay any costs related to participation?

To compensate for any inconvenience that participation in this study may cause, this study will cover the costs of the vision examinations and physical examinations performed during your participation and will provide the study nutritional product free of charge. Treatment and examinations required for any other coexisting diseases, as well as the cost of switching to other treatment due to lack of intervention efficacy, are not included in the free coverage. This study will provide a nutritional subsidy for blood collection of **RMB 100 per visit**. If trial-related injury occurs, corresponding treatment and compensation will be provided in accordance with relevant national regulations.

Will my personal information be kept confidential?

Your medical records will be kept in the hospital. The researchers, supervising authorities, and ethics committee will be allowed to review your medical records. Any public report of the study results will not disclose your personal identity. Within the limits permitted by law, we will make every effort to protect the privacy of your personal medical information.

What treatment options are available if I do not participate in this study?

If you do not participate in this study, or if you withdraw from the study midway, there are still many alternative treatment methods available, such as atropine and orthokeratology (OK) lenses. Orthokeratology lenses are worn overnight to reshape the cornea and slow myopia progression. They have the advantages of being non-surgical and reversible, but there may be slight eye discomfort or a risk of infection. The risks and benefits of different treatments should be evaluated based on your specific condition, and you are advised to discuss them in detail with a professional ophthalmologist to choose the most suitable personalized myopia-control plan.

Must I participate in this study?

Participation in this study is entirely voluntary. You may refuse to participate, or you may withdraw from the study at any time during the study process, and this will not affect the medical care you receive from

your doctor. If you decide to withdraw from the study, please contact your doctor. You may be asked to undergo relevant examinations, which would be beneficial for protecting your health.

If you have any questions regarding your rights and interests, you may contact the Ethics Committee of this hospital at **025-68306360**.

Participant Statement

I have read the above introduction to this study and have fully understood the possible risks and benefits of participating in this study. I voluntarily agree to participate in this study. I will receive a copy of this signed and dated informed consent form.

I **agree** □ or **do not agree** □ that my medical records and clinical specimens related to this study may be used in other research.

Participant Signature: _____

Date: ____ / ____ / _____

Participant Contact Telephone: _____

Witness Signature (if applicable): _____

Date: ____ / ____ / _____

Witness Contact Telephone: _____

Investigator Statement

I confirm that I have explained the details of this study to the participant, particularly the possible risks and benefits of participation, and have answered all questions raised by the participant. The participant has voluntarily agreed to participate in this study. This informed consent form is made in duplicate, and the researcher and the participant will each retain one signed copy.

Study Doctor Signature: _____

Date: ____ / ____ / _____

Study Doctor Work Telephone: _____