Official Title:

Randomized Double-Blind Controlled Trial of Probiotics (Lactiplantibacillus plantarum PD01) for Alleviating the Obesogenic Effect of Microplastics

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Informed Consent Form

Project Title: Randomized Double-Blind Controlled Trial of Probiotics for Alleviating the Obesogenic Effect of Microplastics

Project Leader: Associate Professor Dong Ruihua, School of Public Health, Fudan University

Contact Number: 15800650952

You are invited to participate in a medical research project. This notice provides you with information to help you decide whether to participate. Please read it carefully. If you have any questions, please ask the person in charge of the study.

Your participation in this study is voluntary. This study has been reviewed by the Ethics Committee of this research institution.

1. Research Objective

This study is conducted in cooperation between the School of Public Health of Fudan University and Xiamen Yueyi Biotechnology Co., Ltd.. The study will use a randomized controlled trial to understand whether daily exposure to microplastics (MPs) has potential impacts on human health. It aims to explore whether the intake of Lactiplantibacillus plantarum PD01 can antagonize the potential obesity-related damage caused by MPs in healthy populations, providing a scientific basis for the prevention and nutritional intervention of health hazards caused by MP exposure.

2. Research Process

If you decide to participate in this study, you will first need to participate in a questionnaire survey lasting approximately 10 minutes. You will be asked about your general personal information, anthropometric data, and your current diet and lifestyle behaviors. If you meet the inclusion criteria, you will enter a 6-week randomized controlled trial. You will receive either a probiotic supplement or a placebo (you will not know which one you are taking) to be taken continuously for 42 days.

Probiotic Supplement Formula: 1.8g fructooligosaccharides + 0.2g

Lactiplantibacillus plantarum FABYIO PD01.

Placebo Formula: 2g fructooligosaccharides. Both products have passed relevant safety tests and obtained production licenses.

We will collect biological samples at Baseline (Week 0), Mid-intervention (Week 3), and End-point (Week 6). Samples include approximately 30g of feces, 20mL of urine, and 20mL of blood. The project will provide free comprehensive examinations, including:

Physical Measurements: Body composition analysis (InBody) for waist circumference, hip circumference, body fat percentage, etc..

Biochemical Tests: Routine blood examination and blood biochemical indicators.

Advanced Analysis: Measurement of microplastic levels, gut microbiota (metagenomics), metabolic profiles (metabolomics), and immune-inflammatory parameters.

3. Possible Risks

Blood Collection: Blood will be collected after 12 hours of fasting. Disposable sterile consumables are used. There may be some pain, bruising, and/or bleeding at the puncture site. A few subjects may experience dizziness, and infection may occur in very rare cases.

Supplement Intake: Although L. plantarum PD01 is considered safe, some participants may experience mild gastrointestinal reactions (bloating, mild diarrhea, constipation, gas) in the early stage. These usually resolve spontaneously after 3-7 days. Rarely, allergic reactions (rash, hives) may occur.

4. Monitoring and Response to Adverse Reactions

We have established a complete adverse reaction monitoring mechanism. Researchers will contact you weekly.

Mild Discomfort: If you experience mild bloating, it is usually a normal reaction to gut flora adjustment. It is recommended to take the supplement after meals.

Obvious Discomfort: If you experience persistent diarrhea or vomiting, stop taking

the supplement immediately and contact the team within 24 hours for evaluation.
Severe Symptoms: In extremely rare cases of severe allergic reaction or dyspnea, stop taking the product immediately and call the emergency contact or 120. Medical costs related to adverse reactions will be fully borne by the research team.

5. Possible Benefits

You will receive free biochemical test results (blood routine, urine routine, etc.) and information/consultation regarding MPs and health. This study aims to find effective nutritional interventions to reduce the health impact of MPs.

6. Participation Allowance

Upon completion of all questionnaires, supplement interventions, and sample collections, you will receive a cash subsidy of 600 RMB and 6 boxes of probiotic supplements as a gift. The placebo group will additionally receive a 6-week supply of the probiotic intervention agent as compensation.

7. Confidentiality of Records

Your personal data will be kept confidential and identified by a research number rather than your name. Identifiable information will not be disclosed to members outside the research team without your permission. Research publications will not disclose your personal data.

8. Rights of Research Subjects

You can choose not to participate. You may withdraw at any time. If you have questions or experience discomfort, you can contact the project leader, Associate Professor Dong Ruihua (15800650952). You may also contact the Ethics Committee of the School of Public Health, Fudan University (021-54237051), which represents your interests.

9. Signatures

Research Participant: I have read this informed consent form. I have had the opportunity to ask questions and all questions have been answered. I understand that participation is voluntary.

Participant Signature: _____

Date: _____ / _____ / _____

Investigator: I have accurately informed the participant of this document, and he/she has read this informed consent form accurately and had the opportunity to ask questions.

Investigator Signature: _____

Date: _____ / _____ / _____