

Study title: Effects of Probiotics on Gut Microbiota, Endocannabinoid and Immune Activation and Symptoms of Fatigue in Dancers

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You are invited to take part in a research project carried out within the Doctoral School at the Poznań University of Physical Education. The study has a purely scientific purpose and your participation is voluntary. The aim of this study is to examine whether 12-week supplementation with a probiotic containing *Lactobacillus helveticus* Rosell-52 and *Bifidobacterium longum* Rosell-175 can support recovery after intensive physical exercise, reduce negative physical and psychological effects of heavy training loads, accelerate physiological adaptation to demanding training conditions, and alleviate symptoms related to gastrointestinal discomfort, low-grade inflammation, or mood disturbances. Participation in the study may also help reduce the incidence and duration of infections occurring during periods of intense physical effort.

If you agree to participate, you will be randomly assigned to one of two groups: a group receiving the probiotic preparation SANPROBI® Stress (one capsule daily plus two sachets of powder to be dissolved in water, taken before breakfast and before bedtime), or a placebo group receiving identical capsules and sachets containing only carrier substances such as corn starch and maltodextrins. The supplementation period will last twelve weeks. Throughout this period, you will be asked to report any side effects or health changes.

During the study, blood samples (approximately 25 mL) will be collected from a forearm vein in the fasting state at baseline, after 12 weeks of supplementation, and six months after completion of supplementation. Stool samples (about 20 mL) will also be collected in order to assess the composition of intestinal microbiota, metabolomic markers, and indicators of gut

permeability and inflammation. In addition, you will be asked to complete questionnaires concerning gastrointestinal symptoms, perceived stress and coping strategies, fatigue, and sleep quality. On-site assessments will include anthropometric measurements, physical performance tests, pain threshold tests, and stress-related questionnaires. All examinations will be performed on the premises of the University.

The total duration of your participation is 12 weeks of supplementation and an additional follow-up visit six months later.

The risks related to participation are minimal. Blood collection may cause short-lasting discomfort, bruising, or dizziness. Gastrointestinal discomfort may occasionally occur, although the probiotic strains used are considered safe and well tolerated. Based on current knowledge and extensive safety evaluations, the strains *Lactobacillus helveticus* Rosell-52 and *Bifidobacterium longum* Rosell-175 are regarded as safe for human consumption.

Potential benefits include detailed diagnostic assessments of your health status as well as possible improvement in recovery and well-being following intensive training. Participation in the study may also contribute to scientific knowledge on probiotic supplementation in physically active individuals.

All personal and health data will be treated confidentially. Biological material and questionnaires will be coded in a way that does not allow identification of individual participants. Access to data will only be granted to authorized researchers, auditors, or ethics committee representatives, and results of the study will be published in a way that does not permit identification of any individual.

Participation is voluntary. You are free to withdraw at any time without giving any reason and without any negative consequences. Participants are insured and may be entitled to compensation in the event of harm related to the study.

The probiotic preparation used in this study has undergone extensive safety testing. The active substance consists of two strains of lactic acid bacteria (*Lactobacillus helveticus* R0052 and *Bifidobacterium longum* R0175), which have been selected for their historically safe and beneficial effects on the intestinal flora. Both strains are registered in the CNCM (National

Collection of Microorganism Cultures) at Institut Pasteur in France and have been granted Qualified Presumption of Safety status by the European Food Safety Authority. They are also included on the Australian Therapeutic Goods Administration “List of approved substances” and in Health Canada’s monograph for live microorganisms. Internal research has confirmed the absence of transferable antibiotic resistance genes. Based on current knowledge, these Rosell strains are generally considered safe for human consumption.

If you have questions concerning the study procedures or experience any problems, you may contact the principal investigator.

By signing the attached consent form, you confirm that you have read and understood this information, that you agree to participate voluntarily, and that you may withdraw at any time.

Appendix

e)

Surname and first name of the participant:

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Contact details:

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I hereby declare that I have been informed about the purpose of the intended research and the manner in which it will be conducted.

I understand what it involves and why my consent is required.

I have been informed that I may refuse to give consent to participate in the research or withdraw it at any time without providing any reason, including during the course of the study.

I give my full and informed consent to participate in the research described in the information sheet. I have given this consent in the presence of a witness.

Signature of the participant Signature of the principal investigator

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Signature of the witness to the participant's declaration

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