

Informed Consent Form

Title: Short-Term Effects of Acupuncture on Balance and Quality of Life in Women with Migraine: A Pilot Study

ClinicalTrials.gov Identifier (NCT Number):

Responsible Party: Klaipėda University, Holistic Medicine and Rehabilitation Department

Principal Investigator: PhD Laura Zaliene, Klaipėda University

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Contact Information: +37067499009, laura.zaliene@ku.lt

- 1. Purpose of the Study.** You are invited to take part in a research study. The purpose of this pilot study is to evaluate the short-term effects of acupuncture on balance and quality of life in women with migraine.
- 2. Procedures** - If you agree to participate, you will undergo a series of acupuncture sessions over a defined period. - Before and after the intervention, we will assess your balance, migraine intensity, and quality of life using validated questionnaires and stabilometric testing. - Each session will last approximately [20 minutes].
- 3. Possible Risks and Discomforts** Acupuncture is generally considered safe. Possible minor side effects include: - Mild pain, redness, or bruising at the needle site - Temporary dizziness or fatigue - Rare allergic reactions to sterile needles
- 4. Possible Benefits** You may experience reduced migraine symptoms, improved balance, and enhanced quality of life. However, these benefits cannot be guaranteed.
- 5. Voluntary Participation** - Your participation is entirely voluntary. - You may refuse to participate or withdraw from the study at any time, without giving a reason and without any consequences.
- 6. Confidentiality** - All data collected will be kept confidential. - Your identity will not be revealed in publications or presentations. - Only anonymized data will be analyzed.
- 7. Alternatives** Participation in this study is optional. You may choose not to participate and continue with your usual care.
- 8. Compensation and Costs** There is no financial cost to you. You will not receive payment for participation.
- 9. Ethical Approval** This study has been approved by the Klaipėda University Bioethics Committee and follows the principles of the Declaration of Helsinki.
- 10. Contact Information** If you have questions about the study, please contact: Principal Investigator: [Name, contact details] If you have concerns about your rights as a participant, you may contact the Klaipėda University Bioethics Committee.
- 11. Consent Statement** I have read and understood the information provided above. I have had the opportunity to ask questions, and they were answered to my satisfaction. I voluntarily agree to participate in this study.
12. Participant's Name: _____ Signature: _____
Date: _____
13. Investigator's Name: _____ Signature: _____
Date: _____