INFORMED CONSENT
to PARTICIPATE in a RESEARCH STUDY

[[RAYASANA HEALTH CLINIC / SWISS INTERNATIONAL COLLEGE OF OSTEOPATHY SICO]

PARTICIPANT INFORMATION SHEET

A Double-Armed Randomized Control Trial Evaluating the Effects of OMT on Pain Perception in Patients with Plantar Fasciitis

You are asked to participate, for research purposes, in a study conducted *by Lobelius Erik.*
I believe you can participate in this study and you have communicated through a form and/or via telephone or email that you suffer from clear symptoms associated to plantar fasciitis.
If you agree to take part in this study, you will be asked to complete the questionnaire.
Your participation takes place voluntarily. Before deciding whether to participate, you should read the information below and ask for clarification on anything you do not understand. Please take time to read the following information carefully and discuss it with others if you wish. Only after you have given your written consent you will be able to participate in the proposed study.

What is the PURPOSE of this study?

This research focuses on exploring how osteopathic manipulative treatment (OMT) can affect individuals with plantar fasciitis, a condition causing foot pain. The study's primary aim is to determine if OMT can alleviate pain and enhance overall foot comfort for those with plantar fasciitis. Participants will either receive OMT or be part of a control group for comparison. The outcomes will help understand the potential benefits of OMT in treating plantar fasciitis.

You were selected for this study based on information received through various channels such as flyers distributed at local orthopedic shops or gyms, or via a newsletter. Following a preliminary screening process, it was determined that your symptoms align with the criteria for plantar fasciitis, qualifying you for potential participation in this research.

You are among a carefully selected group of individuals for this study. Including you, there will be a total of 20 participants involved in this research. This controlled number of participants allows for a focused and detailed analysis of the effects of the treatment being studied.

The questionnaire will ask questions about is directly in regard to the condition plantar fasciitis and your perceived pain associated to the condition. The questions will be in regards to a retrospective period of 7 days.

This study has received ethics approval from the AIMO Research Ethics Committee.

What will you be asked to do?

At the end of this consent, if you agree to take part in the research, you will be sent directly to the questionnaire. It will take approximately *10* minutes to complete

What will happen to me if I take part in the research?

If you agree to participate in this research study, the following will occur:
For participants in the OMT group: You are scheduled for a single osteopathic manipulative treatment session at Rayasana Health Clinic, located at Ringvägen 107 in Stockholm. The treatment will approximately last between 45 to 60 minutes. In this session, you will undergo various OMT techniques including myofascial release (both direct and indirect), muscle energy technique, HVLA, and craniosacral techniques. These methods are tailored to address your plantar fasciitis condition. Before the treatment, you will be asked to fill out a questionnaire to assess your pain level over the past week. A week after your treatment, we will request you to complete the same questionnaire again to monitor any changes in your pain levels.
For participants in the control group: Your participation involves filling out a digital questionnaire twice – initially at the start of the study to establish your baseline pain levels, and again one week later to assess any changes. As a gesture of gratitude for your participation, you will be offered a complimentary osteopathic treatment at Rayasana Health Clinic after the study's completion. This free session is our way of ensuring that all participants receive attention and care for their condition.

Please note that the research will be conducted until the beginning of June. Your involvement, particularly if you are in the OMT group, requires only one in-person visit for the treatment session. If you are in the control group, your participation is entirely digital, involving the completion of the questionnaires.

What are the possible disadvantages and RISKS in taking part?

By taking part in this study, you are at risk to feel slight changes in your body during the days that follow the treatment. Feelings like vertigo and tiredness can follow the treatment but are rare and don't last longer than 24 – 48 hours after the treatment.
There is a risk that you might feel embarrassed or exposed during the treatment , however the clinician is aware that this is often the case and will act accordingly if there seems to be a problem, wither by raising the question to see if there is anything that needs to change as the treatment progress or by offering coverage for the patient so that feelings of being exposed of excessively cold are being avoided.

Are there any BENEFITS in taking part?

There is no guarantee that the treatment performed in this study will cure plantar fasciitis. However, it is possible that the treatment may lead to reduced pain and discomfort for the participants. Other than potential pain relief, there is no direct benefit to the participants. This study aims to enhance knowledge on treating plantar fasciitis and could contribute to a better understanding and more effective treatment options for patients with this condition. If the treatments in this study prove to be successful, they could potentially help many individuals suffering from plantar fasciitis, allowing them to return to their daily activities more quickly. The results of this study will benefit scientific understanding and treatment approaches for plantar fasciitis. Furthermore, successfully helping patients recover and return to work, studies, and physical activities would be beneficial for the community at large.

Reimbursement or payment

There will be no payment for taking part in this study , however the participants of the control group will be offered one free treatment of OMT worth 900 sek = approx. 90 euro.

How is information CONFIDENTIALITY guaranteed?

The records from this study will be kept as confidential as possible. No individual identities will be used in any reports or publications resulting from the study. All data collection will be given codes and stored separately from any names or other direct identification of participants. Research information will be kept in locked files at all times. Only research personnel will have access to the files and data collection and only those with an essential need to see names or other identifying information will have access to that particular file.

In order to maintain confidentiality, your name will not be connected to any publication or presentation that uses the information and data collected about you or with the research findings from this study. After the study is completed, your personal collected data will be destroyed.

Participation and WITHDRAWAL

At any time during the study, you have the right to withdraw your consent and discontinue participation without prejudice. To withdraw from the study, we ask you to contact the researcher in writing. If you withdraw from the study, the researcher will stop collecting additional information and data about you.

If the data is collected in an anonymous fashion, the researcher will not be able to remove already collected data from the study.

WITHDRAWAL of the subject by the INVESTIGATOR

The investigator may decide to withdraw you from the study if conditions occur making it necessary. If you observe one or more of the following side effects such as the presence of severe pain during the execution of the test or between one evaluation and another or if you get sick during the study, you may have to abandon it even if you want to continue. The investigator will decide on this and will let you know if it is possible for you to continue participating in the study. The decision may be aimed at safeguarding your health and safety, or required by the study protocol, which may indicate that subjects who develop particular pathologies must be excluded.

NEW findings

During the study, you will be notified of any new findings (positive or negative) that may change the risks or benefits of your participation in the research, or new alternatives that could make you change your mind about continuing it. If you are provided with new elements, you will be asked to renew your consent to continue your participation in the study.

Declaration of TRANSPARENCY

Your osteopath can play the role of investigator in this research and so is concerned with both your health as a patient and the conduct of the study.

The osteopath who combines osteopathic research with osteopathic care involves patients in research only if it is justified by the potential preventive, diagnostic or therapeutic value and if the osteopath has good reason to believe that participation in a study does not affect the health of patients. It is osteopath's duty to protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of the personal information of the human subjects involved in the research. The responsibility for the protection of subjects involved in research must always fall on the osteopath or other health professionals and never on them, even if they have given their consent. (Declaration of Helsinki - Seventh revision, 64th WMA General Assembly, Fortaleza, Brazil, October 2013).

INSURANCE POLICY

The student and/or researcher is covered by an insurance policy in carrying out the research activity. You have the right to make use of the aforementioned insurance policy in case of damage resulting from the specific activities of the trial.

IDENTIFICATION of INVESTIGATORS

If you have any questions about this project or if you have a research problem, you can contact the researcher (s)
Erik Lobelius
0046 (0) 761712347
Eriklobelius @ gmail.com

PARTICIPANTS' RIGHTS

For any questions regarding your rights as a participant in a study, you can contact the Italian Academy of Osteopathic Medicine (AIMO) in Saronno (VA) at Piazzale Santuario, 7, 21047. TEL: +39 0296705292

CONSENT

- I have read (or someone has read to me) the information provided on the previous pages
- I have been given the opportunity to ask questions about the project and my participation
- I voluntarily agree to participate in the research
- I understand I can withdraw at any time and that I will not be penalized for withdrawing
- The procedures regarding confidentiality have been clearly explained to me
- The use of the data in research, publications, sharing and archiving has been explained to me
- Audio, video or other forms of data collection have been explained and provided to me
- I have been given a copy of this form

WITH MY SIGNATURE I AGREE TO PARTICIPATE IN THE STUDY

NAME and SURNAME (PARTICIPANT) _____

PARTICIPANT's signature _____

SIGNATURE for the assent of the PARTICIPANT (≥ 14 years old) _____

NAME and SURNAME (PARENT) _____

PARENT's signature _____

NAME and SURNAME (PARENT)_____

PARENT's signature _____

NAME and SURNAME (legally recognized guardian) _____

SIGNATURE (legally recognized guardian) _____

INVESTIGATOR'S SIGNATURE

I explained the study to the subject and / or his legal representative and answered all his questions. I believe that he / she understands the information contained in this document and voluntarily gives his / her consent to participate.

_____

Name and Surname of the Investigator

_____ _____

Investigator's signature Date

Notes:

- The signature of both parents is required. If there is only one parent or legal guardian, a single signature will be sufficient.
- The signature of "assent" is required in the case of an emancipated minor.