INFORMED CONSENT FOR THE PARTICIPANT IN A NON-COMMERCIAL EXPERIMENT ON THE HUMAN PERSON

Title of the study:

Pilot study: The effect of manual techniques on the psoas muscle for rider sitting balance, tested on the Therapeutic Equine Simulator System.

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Committee for Medical Ethics:

THE MEDICAL ETHICS COMMISSION

Dear participant,

You are invited to voluntarily participate in a study. A group of test subjects is treated with manual techniques relating to the Psoas muscle with the aim of optimizing this muscle in its function in order to positively influence the sitting balance during horse riding. A second group receives valid classic treatment with an electrical device (Cefar Compex).

By eliminating stress factors on the Psoas muscle, it will be able to better perform its function as a stabilizer, which in turn has a positive effect on the sitting balance in the saddle. The synergistic structures (diaphragm, Multifidus muscle, Transversus Abdominis muscle and the pelvic floor muscles) that partly exert their influence on the sitting balance will therefore also be able to perform their function better. The aim of this pilot study is to measure the effect of the changes in the sitting balance by means of a simulation course (walk / trot / canter and jump) to ride on the Therapeutic Equine simulator System before and after the intervention. The obtained data pre- and post intervention will be statistically processed.

Before you agree to participate in this study, it is important that you read this form.

Inclusion criteria: you can participate in this study.

- Age <18 -> 48 years
- BMI > 18.5 - <26.5
- Man / Woman
- Healthy
- Pain-free in the lumbar region
- Low back complaints (pain clinically confirmed in the past 24 months but not present at the time of the study).
- Positive modified Thomas test (with lumbar pressure pad) uni- or bilateral
- Rides for at least 36 months at a higher national / international level

Exclusion criteria: you can NOT participate in this study.

- age > 18 years or <48 years
- BMI > 18.5 or <26.5
- Leg length difference> 10mm
- Medication use (N.S.A.I.D., pain medication, blood thinners, corticosteroids)
- Surgical procedures (abdominal surgery, lower limb prosthesis, lumbar surgery)
- pregnancy
- C.O.P.D.
- Cardiac disease
- Abdominal visceral disease
- Small pelvic visceral disease
- Disc disease lumbar / thoracic / cervical (discitis, radicular / pseudo-radicular disease, herniation)
- Period
- Prostate problem
- Hemorrhoids

- Fractures (lumbar / thoracic / costae / pelvis / femur)
- Cancer
- Infection (fever)
- Osteoporosis
- Inflammation (lumbar / thoracic / costae / pelvis / femur)
- Arteriosclerosis
- Psycho-social (depression)

You can only participate in this study if you meet the inclusion / exclusion criteria above!

1. Study-specific information

This study was approved on ... (date) by the independent Ethics Committee "THE MEDICAL ETHICS COMMISSION"

Purpose and description of the research

This is a scientific study in which a total of 34 people are expected to participate. All participants meet the predetermined inclusion and exclusion criteria. The research takes place in the Reitenhof, Reiten 35 in 2440 Geel, Belgium.

This study aims to improve sitting balance by applying manual techniques to the psoas muscle and to measure this using the Therapeutic Equine Simulator System.

This is an interventional study. This means that manual techniques will be used or that a classic electrostimulation treatment will be performed in order to be able to perform the necessary measurements.

Duration: 60 minutes.

Screening: demographic data, inclusion and exclusion criteria, information about the study, signing a consent form.
Since it is a randomized study, the participants are divided into two groups. You choose an envelope that indicates whether you are assigned to group A or group B.

Group A:

Step 1: General welcome and information about the study. If you agree with this and have understood everything, the following steps will be taken:
signing an information document, inclusion and exclusion criteria are checked out, taking a medical history, performing the modified Thomas test with pressure pad. In the modified Thomas test, hip flexion is measured with a goniometer. The leg length is checked with a measuring tape (anterior superior iliac spine to the lateral malleolus).

Then you can proceed to step 2.

Step 2: You will receive the necessary information on how to operate the Therapeutic Equine Simulator System:
1: in a time span of 2 minutes you will learn to feel the gaits of the horse.
2: information about the sensors and how to drive the simulator: 5 minutes

3: jumping off a course: 5 minutes (including entering the loose riding course)
This information is only intended to be able to perform the test and does not relate to the technical riding aspect during the course. To ensure safety, you will always wear a cap to protect your head and the simulator will be stepped on and off via a step bench. You can always ask the researcher for help with these actions. Riding the course takes four minutes (walk / trot / canter and jumping). During this time no interaction takes place so as not to affect the test results.

Step 3: You will now get some rest until the heart rate has returned to normal. This is checked via the Omron X3 after an interval of three minutes each.

Step 4: Treatment: the following techniques are performed:
• Rebound maneuver on the diaphragm, this technique releases any retractions in the thoracic region and activates the diaphragm globally.
• Doming technique is performed to enhance the function of the diaphragm.
• Nelson's traction manipulation on the thoracolumbar junction to improve the function (mechanical and neurological) of the psoas muscle.
• Fascial release by performing local ponçages on the psoas muscle. The blood flow status of the psoas muscle will thus be positively influenced.
• Positional release (hip flexion plus external rotation) technique of the psoas muscle.
• As a last technique, the psoas muscle will be stretched via a Muscle Energy Technique.
• You will be given a two-minute rest at the end of the treatment.

Step 5: The modified Thomas test with pressure pad is performed again including the hip flexion angle is determined with the goniometer.

Step 6: You will be asked to ride back a four-minute track (walk / trot / canter and jumping) on the Therapeutic Equine Simulator System. Same as in step 2, the necessary attention will be paid to the safety aspects. If you need help getting on or off the Therapeutic Equine Simulator System, this can always be requested from the investigator. Furthermore, no driving information is given in order not to influence the test result.

Group B:

The course of the test will be the same for group B as for group A, with the exception of step 4.

Step 4: You will be positioned in the prone position and 4 adhesive electrodes will be applied paravertebral at the level of the lumbar spine. The electrical appliance that is used, is from the brand: Cefar Compex. The duration of this intervention is 10 minutes.

Duration of the investigation

The study will take sixty minutes per participant and a period of 5 weeks is provided to test all participants.

Pros and cons

The advantage of participating in this study is that it is possible to objectively look at how your sitting balance is at the moment that no intervention has yet taken place and, secondly, it can be compared whether it can be influenced by a treatment. After the study, a copy of the results will be sent to you personally; this can provide you with the necessary insight into which further technical training can be done in order to sharpen the goals in the future. The examination and discussion of the results afterwards is also completely free. However, by participating in this study, we cannot give you any guarantees that you will also benefit directly from this study in the sports field.

Any responses to the techniques used in this study have been reduced to a minimum, but this cannot always be predicted.

2. General information about participation Voluntary participation

If you agree to participate in this study, you will be required to keep this information document and you will be asked to sign the attached consent form.

You participate in this study entirely voluntarily and you have the right to refuse to participate in it.

You also have the right to discontinue your participation in the study at any time, even after signing the consent form. You do not need to state a reason for this. Withdrawing your consent will not cause any harm or loss of benefits.

Your participation in the study may also be discontinued at any time by the investigator(s), the Ethics Committee or the sponsor without your consent. Possible reasons for such a decision may include:

- You are not following the instructions for participating in the study.
- Your further participation appears to be harmful to you.
- During the examination it is established that you do not or no longer meet the

conditions for participation.

Liability and insurance

If you suffer damage as a result of your participation in this study, you or your entitled parties will be compensated by the sponsor of this study for this damage, in accordance with the applicable Belgian law. You do not need to demonstrate an error.

The client has taken out flawless insurance that covers any damage that may result from this investigation. You or your entitled parties can sue this insurer directly for this at any time.

Costs and compensation

This study will not incur any additional costs for you. All costs arising from your participation in the study are for the account of the researcher or the client. Costs that are not related to the study, but are part of your treatment, remain at the expense of you and your health insurance fund and / or insurer.

Protection of your privacy

Your identity and your participation in this survey will be treated in strict confidence. You will not be identified by name or otherwise in any files, results or publications related to the study.

In order to guarantee your privacy with regard to the storage and processing of the data in the context of this study, your data will be pseudonymised. This means that your name, first name, date of birth and place of residence will be replaced by a code. All further processing is done on this pseudonymised data. The link between the code and your person will be preserved. This link is only used to be able to feedback certain information to you in your own interest.

Protection of your personal data

If you agree to participate in this study, this means that you consent to the use of your personal data collected in the context of this study.

You can withdraw your consent to collect and process your data at any time. If your study participation is stopped prematurely, your original consent will allow the use of the data collected about you in relation to the period you were included in the study.
Only persons directly involved in the study will have access to your personal data. Your data will not be passed on to third parties.

The researchers will keep your data for a period of 10 years.

You have the right to ask the researcher what data is collected about you in the context of the research and what the purpose is. You can ask to correct or delete certain data, or to stop using your data.
All data collected from you will be treated in accordance with the “Guidelines for the protection of individuals regarding the processing of personal data” and the applicable national laws. The European General Data Protection Regulation (AVG / GDPR) - EU2016 / 679) and the Belgian law that further develop this regulation.

As the client of the study, Geert Laenen is responsible for the processing of your personal data. You can ask questions regarding the management of your data via e-mail: geert.laenen@ki-os.be

We hope that this document has provided you with sufficient information about the study. You have the right to ask additional questions at any time about the content, purpose or course of the research, about the possible and / or known advantages and disadvantages that this research entails for you, etc. contact the researcher(s) (and the contact person mentioned above).