KABAT TRAINING PROGRAM IN DIAGONAL PATTERN WITH ELASTIC BANDS FOR SHOULDER IN AMATEUR SWIMMERS. A RANDOMIZED CONTROLLED CLINICAL TRIAL

THERA2020

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INFORMATION SHEET FOR THE SUBJECT

Project title: KABAT TRAINING PROGRAM IN DIAGONAL PATTERN WITH ELASTIC BANDS FOR SHOULDER IN AMATEUR SWIMMERS. A RANDOMIZED CONTROLLED CLINICAL TRIAL

Please read this information sheet carefully:

- Today you will be invited to participate in this research project that is being carried out in the Universidad Europea de Madrid.
- If you agree to take part in this study, you will be asked to sign the attached consent form. Please read the information carefully.
- Your participation in this study is completely voluntary and you can decide not to participate or change your decision and withdraw your consent at any time during the study, without altering your relationship with your doctor or anyone responsible for the project, nor causing any harm.
- Do not sign the consent form until you are sure you understand the nature of the study and what it involves, and you are sure you want to be involved. You will then be given a written copy of this information document and informed consent.
- Your participation in this study does not imply any alteration in your usual training program that you carry out.

WHAT IS THE OBJECTIVE OF THIS RESEARCH PROJECT?

To analyze the efficacy of the proprioceptive neuromuscular facilitation training with Theraband® on muscle strength, range of motion, scapular displacement and muscular balance of rotator cuff in male amateur swimmers between 18 and 33 years of age.

WHAT DO I COMMIT TO IF I DECIDE TO PARTICIPATE?

In this study, 30 swimmers will be selected, who will be evaluated by a researcher and will be randomly included in two groups:

- Experimental group: 15 patients who will carry out 2 training sessions of the external rotator muscles of the shoulder per week, and who will be evaluated before starting treatment, after the end of the 8-week treatment period, and after the 2-week follow-up period.
- Control group: 15 patients who will carry out no session, and who will be evaluated in the 3 periods described.

If you belong to the experimental group, you will have to perform 2 physiotherapy sessions per week using Theraband®, for a period of 8 weeks. Sessions will last approximately 4

minutes. Whether you belong to the experimental group or the control group, you will be evaluated by a researcher before and after the study period.

You will continue with the usual training program and will not require any extraordinary procedure except for attendance at the evaluations.

This study will serve to analyze the effect of training with Theraband elastic bands® in swimmers. There may be no benefit to you from participating in this study, although the information you provide may benefit other patients in the future.

WHO CAN I CONTACT TO RESOLVE DOUBTS OR IN CASE OF NEED?

We invite you to ask all the questions you consider appropriate to the main investigators of this study.

HOW CAN I LEAVE THE STUDY IF I CHANGE MY MIND?

Adherence to this research is completely voluntary. You may leave the study at any time you wish, and this will in no way modify your right to be treated under the same conditions as if you were still in this project.

HOW IS CONFIDENTIALITY GUARANTEED?

The confidentiality of the data will be guaranteed by following the laws below:

-Organic Law 15/1999 of December 13 on the Protection of Personal Data and Royal Decree 1720/2007 of December 21.

-Images: Organic Law 1/1982, of May 5, on civil protection of the right to honor, personal and family privacy, and one's own image.

- Relationship of the identification code and the patient assigned to it.

PARTICIPATION / VOLUNTARY ABANDONMENT

Your participation in this study is voluntary. You have complete freedom to refuse the offer to participate, as well as to withdraw your consent to the study at any time. You will have enough time to ask questions about the details of the study and to decide whether or not you want to participate.

Once the data collection for the study has begun, if you decide to withdraw your consent for the study, it is enough to speak to a researcher. You will maintain the right to refuse to collaborate in the data collection and may demand the removal of all information related to the course of your disease collected in the sponsor's database so that it is not included in the analysis.

INFORMED CONSENT DOCUMENT

Title: **KABAT TRAINING PROGRAM IN DIAGONAL PATTERN WITH ELASTIC BANDS FOR SHOULDER IN AMATEUR SWIMMERS. A RANDOMIZED CONTROLLED CLINICAL TRIAL**

I, Mr/Mrs _____, with DNI: _____:

- I have clearly and truthfully read and understood the study to which I have been invited to participate.
- I have been informed of the protocol for pre and post study measurements and how the training will be carried out.
- I agree to participate freely and voluntarily in this project.
- I promise to be evaluated before and after the intervention and to participate in the treatment according to the times and modalities provided with the researchers of the study and the club to which I belong.

Us, the investigators we have explained to Mr./Mrs. _____ the nature and purposes of the research cited above; we have explained to you the risks and benefits of your participation . We have answered your questions to the extent possible and asked whether or not you have any further questions about the study. I accept that I have read and know the corresponding regulations for conducting research with human beings and I adhere to them.

On _____ on __ of _____ of 20__.

B/D. _____

D. _____

Only in case of revocation of consent:

I, D/Mrs. _____ with DNI _____, I do not give authorization to agree to participate in this study, or I revoke prior consent, if granted. Mr/Ms. _____