GENERAL STUDY INFORMATION AND INFORMED CONSENT

UNIVERSITY CEU CARDENAL HERRERA

Principal investigator: Dr. José Miguel Soria López

TITLE: Cross-cultural adaptation of the TENDINopathy Severity Assessment–Achilles. (TENDINS-A) for the Spanish population and evaluation of its reliability and validity in accordance with COSMIN recommendations.

Research and Ethics Committee of CEU Cardenal Herrera University Number: CEEI 24/558

NCT ID: xxxxxxxxxxx

DATE: Nov 28, 2025

GENERAL STUDY INFORMATION

TITLE: **Cross-cultural adaptation of the TENDINopathy Severity Assessment–Achilles. (TENDINS-A) for the Spanish population and evaluation of its reliability and validity in accordance with COSMIN recommendations: A Methodological / Psychometric validation study**

Mr. Dr. José Miguel Soria López, Biologist, principal investigator and researcher reports that:

This project aims to carry out a Spanish cross-cultural adaptation of the TENDINS-A questionnaire, a patient-reported outcome measure (PROM) originally developed in English.

To achieve this, an initial translation process will be performed following Beaton's recommendations, resulting in a first translated version to be used for the validation studies of the questionnaire in Spanish.

The study will be conducted in collaboration with various sports organizations and physiotherapy clinics. Individuals diagnosed with Achilles tendinopathy who consent to participate will be asked to complete three questionnaires at baseline (VISA-A, FAOS, and TENDINS-A) and, 48 hours later, the TENDINS-A retest.

The data collected across groups and time points will allow the determination of whether the translated questionnaire demonstrates reliability, validity, responsiveness, and feasibility comparable to those of the original version.

The general data of the subject will be collected (name, age, sex, physical variables and clinical history). The article must be sent with comfortable clothes The day that sea cited by the researcher, previous notice. Personal data is recognized in this study.

The personal data are confidential, apply to the protection of personal data (Organic Law 15/1999, December 13) and any other thing that may be applicable.

This study was approved by the Research and Ethics Committee of CEU Cardenal Herrera University (CEEI24/558)

INFORMED CONSENT

Mr/Mrs..... with Number identification .... freely and voluntarily, I DECLARE:

That I have read the information contained in this document about the general information of the study.

I have been informed that all tests are simple to perform and do not produce harmful effects on health. They will be carried out in appropriate facilities and will be carried out by qualified and specialized personnel.

I have also been informed that, the data collected in this study will be treated confidentially, applying the current legislation on protection of personal data (Organic Law 15/1999, of December 13) and any other applicable.

Therefore, I give my consent and I authorize Mr. José Miguel Soria López, to carry out the detailed study in this document with the help of the necessary personnel with the appropriate qualification and specialization.

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STUDY PROTOCOL PLAN AND STADISTICAL ANALYSIS PLAN (SAP)

UNIVERSITY CEU CARDENAL HERRERA

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STUDY PROTOCOL PLAN

Objectives:

The objectives of our study have been the following:

General:

• To perform the cross-cultural adaptation of the TENDINS-A questionnaire into the Spanish language.
• To validate the content of the Spanish version of the TENDINS-A questionnaire in relation to the original version.
• To assess its psychometric properties in the target Spanish population.

Volunteers who want to participate in the study will read the general information of the study and sign the informed consent to participate in the study.

Once the informed consent has been read and delivered, the evaluator will check that they meet the inclusion criteria. After the data collection, a randomization (Epidat V4.0) of the selected subjects will be carried out to assign them to one of the intervention groups.

Patients must present Achilles pathology and will be recruited through a network of physiotherapy clinics distributed across Spain.

The physiotherapist responsible for their treatment will invite them to participate in the study by providing a QR code granting access to all relevant study documentation. This documentation will include a checkbox in which the patient must indicate that, after reading all the pertinent information, they consent to participate. Without this explicit consent, marked via the checkbox, participation will not be possible.

Once consent is provided, the patient will gain access to three questionnaires to be completed at the same time: VISA-A, FAOS, and TENDINS-A. After 48 hours, they will receive a link to complete the TENDINS-A retest.

When the participant has completed all four questionnaires (VISA-A, FAOS, TENDINS-A, and the TENDINS-A retest), their participation in the study will be considered complete.

The sample size will be calculated following COSMIN recommendations, aiming for a minimum of more than 100 participants to ensure excellent reliability.

Statistical Analysis Plan (SAP)

The statistical analyses required for the structural validation and assessment of the psychometric properties will be performed using IBM SPSS Statistics (v29.0.2.0), Jamovi (v2.3.28.0), or Microsoft Excel (v16.77.1).