

Predicting pain recovery in patients with acute low back pain: A clinical prediction model validation study

The research project, presented to UNICID Ethics Committee, titled as PREDICTING PAIN RECOVERY IN PATIENTS WITH ACUTE LOW BACK PAIN: A CLINICAL PREDICTION MODEL VALIDATION STUDY. It is a Post-Doctorate research under the supervision of Prof. Dr. Leonardo Oliveira Pena Costa.

The research project aims at determining the utility of this new clinical prediction model in the Brazilian population, based on the report of the model performance (discrimination and calibration) for predicting pain recovery in 1 week, 1 month and 3 months in patients with acute low back pain that remains with pain after 1 week after seeking clinical care.

There is low probability of risks once the 420 participants are adults over 18 years old. These participants will sign a Participant Information Consent Form with the guarantee of anonymity and opt-out option for any reason.

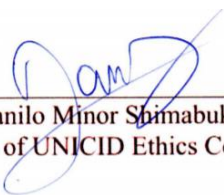
This is a clinical prediction model validation study. All participants will receive a pain diary to be filled with pain intensity information in a numeric scale of 11 points (ranging from 0 to 10), every day, for a 3-month period. The patients will answer weekly follow-ups about last week's pain diary information. The follow-ups will be made by e-mail, text messages, WhatsApp texts or calls (according to patient preference), until the patients recover or for the period of 3 months in case of non-recovery. At the first follow-up, a week after the consultation, which would be considered as the "clinical revision", the patients will be contacted by phone to answer the questions related to the clinical prediction model (referring to depression and current pain intensity) and the information of the last week's pain diary information.

The documentation offered to the analysis process of the research is complete. It has the acceptance of the Masters and Doctoral Programs in Physical Therapy at UNICID – Prof. Dr. Leonardo Oliveira Pena Costa, as well as the signature of UNICID's Dean Prof. Dr. Luiz Henrique Amaral. There is also approval of two responsible for Medical Assistance Institute to State Public Servers – Superintendency – Dr. Roberto Dantas Queiroz (Orthopedics and Traumatology Service Director) and Dr. André Luiz Freitas Silva (Direction HSPE – IAMSPE), institution where patients will be recruited with age over 18 years old, seeking care for non-specific acute low back pain (with pain duration up to 3 months), with or without radiated pain to other inferior member(s), with moderate pain intensity measured by an adaptation of item 7 of SF-36. Will be excluded: pregnant women and suspicion of severe spinal cases (fractures, tumors, inflammatory diseases and nerve compression). There is also a declaration from the research Co-participant Institution – Medical Assistance Institute to

State Public Servers (IAMSPE) from Dr. Kátia Antunes, Director of State Public Server Hospital Francisco Morato de Oliveira (HSPE-FMO).

None

The research PREDICTING PAIN RECOVERY IN PATIENTS WITH ACUTE LOW BACK PAIN: A CLINICAL PREDICTION MODEL VALIDATION STUDY has conditions to be developed, considering the exigencies of this Ethics Committee.



Danilo Minor Spimabuko
Member of UNICID Ethics Committee