

Official title: Effectiveness of Implementing Shared Decision-Making on Quality of Care Among Patients With Lumbar Degenerative Diseases.

NCT number: NCT03679494

Document date: September 25, 2018

## Background:

Shared decision making (SDM) is a patient-centered and evidence-based model of clinical decision making. The feature of SDM is that clinicians work together with patients to plan the most appropriate and practical treatment for patients based on the patients' preferences and values. Recently, SDM has been implemented throughout the world to improve patients' health literacy and to have a better understanding of the treatment options, thereby improving patient-doctor communication and promoting the quality of care.

Lumbar degenerative disease is a critical public health issue in the aging society. SDM now becomes an important process because there is no consensus of evidence-based practice guidelines among the multiple complex treatment options for patients with lumbar degenerative disease. In addition, there is a lack of evidence to support the effect of patient decision aids (PDAs) to promote the quality of healthcare for patients with lumbar degenerative disease in Taiwan.

## Purposes:

This project has two purposes. The first purpose is to develop a multimedia interactive patient doctor communication system called the Taiwan Shared Decision Making for Lumbar Spine Treatment (Taiwan SDM LumST). The second and ultimate purpose is to conduct a cluster randomized controlled trial (cRCT) for the validation of the integrated SDM model and the effectiveness of SDM related outcome indicators.

## Methods:

In the first year of the 3-year project, investigators will develop the SDM communication teaching materials, PDAs, as well as the computerized platform of Taiwan SDM LumST through focus groups and consensus meetings. In the second to third year, investigators will recruit 130 patients with lumbar degenerative disease to participate in double blind cRCT in the affiliated hospitals of Taipei Medical University. Investigators will use Analysis of covariance (ANCOVA) and Pearson's chi-squared test were used to analyze the difference in outcomes between two groups. Using structural equation modeling to validate the factors of the SDM model and adopt generalized linear regression models with generalized estimating equations to examine the immediate, short-term, and long-term benefits of the Taiwan SDM

LumST in implementing the SDM model among patients with lumbar degenerative disease.

Expected results:

Investigators expect that the implementation of the Taiwan SDM LumST system will significantly improve the patients' decision preference, health literacy in the care of lumbar degenerative disease, and self-efficacy in SDM. It will also promote the health care quality and health outcomes (e.g., participation in SDM, quality of decisions, regret in decisions, health outcomes, and quality-of-life) in patients with lumbar degenerative disease.

Expected impacts on the society, economy, and academic developments:

The Taiwan SDM LumST will be an efficient and effective way to facilitate patient doctor communication and thereby, promote health outcomes and improve the quality of decisions made by patients with lumbar degenerative disease. No computerized interactive PDA of SDM system for patients with lumbar degenerative disease exists in Taiwan yet. Thus, our system would be the first in Taiwan for the lumbar degenerative population. Investigators hope that the Taiwan SDM LumST will not only contribute to academic research, but also facilitate SDM between patients and healthcare professionals in order to improve patient safety and enhance the quality of care in Taiwan.