

Cover letter**Title of the study**

Are the results of patient reported outcome measures after spine surgery influenced by recall of preoperative scores? – a randomized controlled trial

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Study protocol

Title of the study

Are the results of patient reported outcome measures after spine surgery influenced by recall of preoperative scores? – a randomized controlled trial

Objective

To analyse the impact of recall bias of preoperative status on postoperative PROMs of patients submitted to surgery due to degenerative spine disease.

Methods

All adult patients with valid preoperative PROMs scores submitted to spine surgery due to degenerative pathology from 01.2019 to 04.2020 at our center were included in the study and received questionnaires with a letter of consent.

To evaluate the impact of recall bias on the scores of postoperative PROMs the patients of the intervention/recall group received postoperative questionnaires that included the preoperative answers for every individual question, whilst the control/no-recall group answered postoperative questionnaires without the preoperative responses.

In preoperative and postoperative evaluation, to assess surgical outcome and disability, lumbar spine patients filled the back Core Outcome Measures Index (COMI) and Oswestry Disability Index (ODI) questionnaires, while patients with cervical degenerative spine disease completed the neck surgical COMI and the Neck Disability Index (NDI)

All adult patients with valid preoperative PROMs scores submitted to spine surgery due to degenerative pathology from January 2019 to April 2020 at our center (spine unit of a neurosurgical department in a Portuguese university hospital) were included in the study and received PROMs questionnaires with a letter of consent.

The primary outcome of the study was the postoperative COMI score, while the secondary outcomes were the postoperative NDI or ODI and EQ-5D scores.

Effect size was obtained according to the quotient of minimal detectable change (MDC) for COMI and the standard deviation (SD) of the minimal clinical important difference (MCID).