Appraisal | Trial Protocol

Back school or brain school for patients undergoing surgery for lumbar radiculopathy? Protocol for a randomised, controlled trial

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Abstract

Introduction: Despite scientific progress with regard to pain neuroscience, perioperative education tends to stick to the biomedical model. This may involve, for example, explaining the surgical procedure or 'back school' (education that focuses on biomechanics of the lumbar spine and ergonomics). Current perioperative education strategies that are based on the biomedical model are not only ineffective, they can even increase anxiety and fear in patients undergoing spinal surgery. Therefore, perioperative pain neuroscience education is proposed as a dramatic shift in educating patients prior to and following surgery for lumbar radiculopathy. Rather than focusing on the surgical procedure, ergonomics or lumbar biomechanics, perioperative pain neuroscience education teaches people about the underlying mechanisms of pain, including the pain they will feel following surgery. **Research objectives**: The primary objective of the study is to examine whether perioperative pain neuroscience education ('brain school') is more effective than classic back school in reducing pain and improving pain inhibition in patients undergoing surgery for spinal radiculopathy. A secondary objective is to examine whether perioperative pain neuroscience education is more effective than classic back school in: reducing postoperative healthcare expenditure, improving functioning in daily life, increasing return to work, and improving surgical experience (ie, being better prepared for surgery, reducing incongruence between the expected and actual experience) in patients undergoing surgery for spinal radiculopathy. **Design**: A multicentre, two-arm (1:1) randomised, controlled trial with 2-year follow-up. **Participants and setting**: People undergoing surgery for lumbar radiculopathy (n = 86) in two Flemish hospitals (one tertiary care, university-based hospital and one regional, secondary care hospital) will be recruited for the study. **Intervention**: All participants will receive usual preoperative and postoperative care related to the surgery for lumbar radiculopathy. The experimental group will also receive perioperative pain neuroscience education comprising one preoperative and one postoperative individual educational session plus an educational booklet. **Control**: Participants in the control group will receive perioperative back school on top of usual preoperative and postoperative care, comprising one preoperative and one postoperative individual educational session plus an educational booklet. **Measurements**: Self-reported pain and endogenous pain modulation (including measurements of simultaneous cortical activation via electroencephalography) will be the primary outcome measures. Secondary outcome measures will include daily functioning, return to work, postoperative healthcare utilisation and surgical experience/satisfaction. Psychological factors will be measured as possible treatment mediators. **Procedure**: All assessments will take place in the week preceding surgery (baseline), and at 3 days and 6 weeks after surgery. Intermediate and long-term follow-up assessments will take place at 6, 12 and 24 months after surgery. **Analysis**: All data analyses will be based on the intention-to-treat principle. Repeated measures AN(C)OVA analyses will be used to evaluate and compare treatment effects. Baseline data, treatment centre, age and gender will be included as covariates. Statistical, as well as clinically, significant differences will be evaluated and effect sizes will be determined. In addition, the numbers needed to treat will be calculated. **Discussion**: This study will determine whether pain neuroscience education is worthwhile for patients undergoing surgery for lumbar radiculopathy. It is expected that participants who receive perioperative pain neuroscience education will report less pain and have improved endogenous pain modulation, lower postoperative healthcare costs and improved surgical experience. Lower pain and improved endogenous pain modulation after surgery may reduce the risk of developing postoperative chronic pain.

Trial registration: ClinicalTrials.gov. **Registration number**: NCT02630732. **Was this trial prospectively registered?** Yes. **Date of trial registration**: 25 November 2015. **Funded by**: Applied Biomedical Research Program, Institute for the Agency for Innovation by Science and Technology (IWT), Belgium. **Funder approval number**: IWT-TBM project no. 150180. **Anticipated completion date**: 30 April 2019. **Provenance**: Not invited. Peer reviewed. **Corresponding author**: Vrije Universiteit Brussel, BE-1090 Brussels, Belgium.

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