Multimodal prehabilitation combined with perioperative enhanced recovery after surgery care for older patients undergoing spinal fusion surgery in china: protocol for a multi-center randomized controlled trial (PRACTICE trial)

Informed Consent Form

Study Title: Multimodal prehabilitation combined with perioperative enhanced recovery after surgery care for older patients undergoing spinal fusion surgery in China: Protocol for a multi-center randomized controlled trial (PRACTICE trial)

Study Purpose: The purpose of this study is to evaluate the effectiveness of a multimodal prehabilitation program combined with perioperative enhanced recovery after surgery (ERAS) care on outcomes in older patients undergoing spinal fusion surgery.

Date: 2024-04-01

Introduction:

Spinal fusion surgery is one of the most commonly used treatments for degenerative spinal diseases. Recent studies using multicenter data have shown that the increase in spinal fusion for spinal degenerative diseases was highest among patients aged over 75 years. In addition to the comorbid risk factors that older patients share with younger ones, older patients may also have malnutrition and cognitive or functional impairment. The accumulation of geriatric frailty and various geriatric syndromes in older patients leads to decreased physiological reserves, resulting in a challenging recovery process after spine surgery.

Moreover, symptomatic degenerative spinal disorders are associated with a high prevalence and incidence of frailty in community-dwelling older adults. Walking intolerance caused by pain or numbness due to degenerative spinal disorders may lead to decreased physical activity, which might subsequently worsen age-related muscle weakness and frailty. Therefore, individualized preoperative optimization strategies should target medical,

functional, cognitive, and nutritional conditions in spine surgery

We are conducting a research study that aims to improve the recovery and outcomes of older patients undergoing spinal fusion surgery. The study will evaluate a new approach that combines prehabilitation (a program of physical, nutritional, and psychological preparations before surgery) with ERAS care (a set of standardized guidelines to optimize the perioperative period).

Study Procedures:

If you are eligible and choose to participate in this study, you will be randomly assigned to one of two groups:

Control Group:

You will receive standard care before and after surgery. Participants randomized to the control group will receive perioperative ERAS care. The ERAS program consists of pre-admission and perioperative multimodal management and was implemented by the orthopedic department in January 2019. Our ERAS program includes pre-admission education and consultation, risk screening and optimization, multimodal analgesia, minimal intravenous fluid administration, pre-emptive analgesia, early removal of urinary tube, early physical rehabilitation, avoiding mechanical bowel preparation, no prolonged fasting, nutritional management, and antithrombotic prophylaxis. Pre-admission intervention include education on smoking and excessive drinking cessation, available counseling services, optimization of chronic disease, and nutritional assessment and support (only through nutritional education). ERAS care will include guidelines for optimizing pain management, nutrition, physical activity, and other aspects of recovery.

Intervention Group:

You will receive a multimodal prehabilitation program followed by perioperative ERAS care. Participants randomized to the intervention group will receive PREERAS management. During the planning phase of the study, we assembled a multidisciplinary team consisting of geriatrician, spine surgeons, nurses, rehabilitation specialists, anesthesiologists, neurologists, nutritionist, and social workers. Then, the PREERAS programme was conducted based on previous studies and surgical guideline. PREERAS mainly consists of Vivifrail multicomponent exercise, nutritional intervention, cognitive prehabilitation and brain protection.

Potential Benefits:

Participants in the intervention group may experience faster recovery, reduced complications, and improved overall outcomes compared to those in the control group. The results of this study may help improve the care of older patients undergoing similar surgeries in the future.

Potential Risks:

Participation in the study carries the same risks as any surgical procedure, including but not limited to infection, bleeding, and adverse reactions to anesthesia. Additionally, there is a possibility that some participants may experience no benefit or even negative outcomes from the intervention.

Confidentiality:

All information collected during the study will be kept confidential to the extent permitted by law. Your identity and personal data will be known only to the research team members who are involved in this study.

Withdrawal Rights:

You have the right to withdraw from the study at any time without affecting your routine care. If you choose to withdraw, your participation will be documented, and you will be monitored for any study-related risks that may require additional follow-up.

Privacy Issues:

If you decide to participate in this study, your participation in the study and your personal information during the study will be kept confidential. Your biospecimen will be identified by the study number and not by your name. Information that identifies you will not be shared with anyone outside of the research team unless you give your permission. All study members and the study sponsor are asked to keep your identity confidential. Your file will be kept in a locked filing cabinet and will be accessible only to researchers. If necessary to ensure that the study is conducted in accordance with the regulations, members of the government regulatory or ethical review committee will be given access to your personal data at the research unit as required. No personal information about you will be disclosed when the results of this study are published.

The research physician may terminate your continued participation in this study if you need other treatment, or if you do not follow the study plan, or if a study-related injury occurs or for any other reason.

Questions:

If you have any questions about the study, its procedures, or your rights as a participant, please contact us.

Informed consent signature page

- I have read this informed consent form.
- I had the opportunity to ask questions and all of them were answered.
- I understand that participation in this study is voluntary.
- I can choose not to participate in the study or withdraw at any time by notifying the researcher without discrimination or retaliation, and any of my medical treatment and rights will not be affected as a result.
- The study physician may terminate my continued participation in this study if I need other treatment, or if I do not comply with the study plan, or if a study-related injury occurs or for any other reason.
- I will receive a signed copy of the Informed Consent Form.

Subject's Name: _____

Subject's signature: _____

Date: _____

- I have accurately communicated this document to the subject, requesting that he/she has carefully read this informed consent form and that any questions or issues raised are carefully answered.

Researcher's Name: _____

Researcher's signature: _____

Date: _____