Centre intégré universitaire de santé et de services sociaux du Nord-de-l'Île-de-Montréal
Québec

AFFILIÉ À Université de Montréal

INFORMATION AND CONSENT FORM

Title of the research project:
Early mobilization after elective spinal surgery: a prospective randomized trial of in-bed cycling on the day following surgery

Protocol number: 2020-2002

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Funding:
This research project is funded by the Medtronic Chair in Spinal Trauma of the Université de Montréal, managed by Dr. Jean-Marc Mac-Thiong at Hôpital du Sacré-Cœur de Montréal, CIUSSS du Nord-de-l'Île-de-Montréal.

Preamble

You are being invited to participate in a research project because you are scheduled to undergo elective spinal surgery. Before agreeing to take part in this study and signing this information and consent form, please take the time to read, understand, and carefully consider the information below.

This form may contain words that you do not understand. You are encouraged to ask any questions you consider useful to the researcher responsible for the project or to any other member of the research team, and to request clarification of any word or information that is unclear.

Simultaneous participation in more than one research project could be harmful. If you are currently participating in another research project, please inform the researcher.

1. Nature and objectives of the research project

Spinal surgery is often debilitating and painful. Several clinical studies suggest that initiating certain movements or activities early after spinal surgery leads to better outcomes in terms of care (length of hospital stay, complications, etc.) and recovery (motor function, pain, etc.). Some studies have shown that early mobilization through movement sessions or patient transfers provides significant benefits for maintaining and recovering functional abilities (i.e., the ability to walk and move), as well as for pain management and return home. It has also been demonstrated that leg movement in bed is safe and feasible as soon as surgery is completed.

At Hôpital du Sacré-Cœur de Montréal (HSCM), standard postoperative mobilization consists of getting the patient out of bed and into a chair. Physiotherapy usually begins 2 to 3 days after surgery to assess the patient's functional capacity. If functional abilities are preserved (i.e., the patient is able to walk and transfer independently), the patient is discharged home. Otherwise, physiotherapy exercises are initiated and the patient is referred to intensive functional rehabilitation. To date, with standard care, only about two thirds of patients maintain good functional capacity. However, according to the literature, after such surgery, a higher proportion of patients (90%) could return home if they receive appropriate early mobilization the day after surgery.

Several early mobilization strategies have been studied in the literature, such as walking the patient or performing leg exercises in bed. However, each of these methods presents challenges related either to patient compliance (difficulty level too high) or to the availability of human resources (insufficient staff to provide the exercises).

Studies of early in-bed mobilization using a cycling device in intensive care unit patients have demonstrated effectiveness. However, these studies were not conducted in patients undergoing spinal surgery. Therefore, the objective of this research project is to evaluate early leg

movement in bed using a portable cycling device after elective spinal surgery and to assess its impact on patients' functional capacity.

The primary objective is to compare mobility after elective spinal surgery between patients who perform an in-bed cycling session and those who do not.

A total of 88 participants will be recruited at HSCM for this research project, divided into two groups of 44 patients.

2. Study procedures and methods

Patients who walk independently are eligible for the study (i.e., those who are able to walk without assistance from another person or a wheelchair). These patients will complete a questionnaire with a research team member regarding walking ability and functional independence (Functional Independence Measure and SF-36 quality of life questionnaire).

On the day of surgery, in the postoperative period, research staff will visit you to confirm your eligibility. They will provide you with a Fitbit Inspire HR activity tracker. You will be asked to wear this watch on your left wrist at all times until the second postoperative day.

After surgery and once you have consented to participate in the study, you will be randomly assigned (randomization) to one of the two study groups: the group receiving standard care only, or the group receiving an in-bed cycling session in addition to standard care.

If you are assigned to the intervention group (cycling session), the procedure will be explained again, along with the importance of your cooperation. You will then be positioned comfortably on the bed-adapted cycle. The device has two modes: an active mode, in which you pedal independently, and a passive mode, in which the motor assists you in reaching the target speed. In both active and passive modes, the target speed is 40 revolutions per minute (rpm), which must be maintained for a 30-minute session. This target has been shown to be safe and will be reached progressively. If you begin the session in active mode and feel that you need assistance, the motor can be activated to help you maintain 40 rpm.

Before, during, and after the session, your pain level will be assessed and your vital signs will be monitored using a blood pressure cuff and an oximeter (a device that measures blood oxygen levels).

Several predefined stopping criteria allow the session to be interrupted at any time. These criteria are based on previous studies conducted in intensive care patients and have been adapted for this study. The session will be stopped in the event of abnormal vital signs (oxygen desaturation, abnormal heart rate increase or decrease, or abnormal blood pressure). You are asked to inform the staff if you experience pain or discomfort (chest pain, abnormal shortness of breath, breathing difficulty, other physical pain, malaise, or agitation) so that the cycling session can be stopped. You may also request that the session be stopped for any other reason.

Whether you are in the control or intervention group, your mobilization will be evaluated over a 24-hour period on the day following surgery.

On the second day after surgery, a research team member will visit you to ask you to rate your pain level using a 10-point visual analog scale and to collect the activity tracker. During this visit, you will also complete questionnaires on walking ability and functional independence.

Regardless of the group to which you are assigned, certain information will be collected from your medical record: sociodemographic data (age, height, weight, ethnic origin), medical history, neurological examination performed before and after surgery, type of surgery, and underlying pathology. Complications occurring during hospitalization, treatments received, and length of hospital stay will also be collected.

2.1 Equipment

- Fitbit Inspire HR activity tracker
- Portable cycle ergometer

To monitor vital signs during the intervention, a blood pressure cuff and a digital oximeter (device to measure pulse and blood oxygenation) will be used for participants in the intervention group.

3. Risks and inconveniences associated with the research project

We do not anticipate any adverse effects related to the intervention. The literature reports that cycling in critically ill patients does not increase pain. However, this has never been studied in your patient population. We therefore plan to closely monitor this parameter during the intervention. One possible inconvenience you may experience after the session is fatigue.

During the intervention, all participants will be supervised by qualified members of the research team (physicians from the research team and a clinical monitor in spinal orthopedics). If you experience discomfort, malaise, agitation, or if your physiological parameters become unstable, the cycling session will be stopped immediately.

4. Benefits

You may or may not derive a personal benefit from participating in this research project. However, the results will contribute to the advancement of scientific knowledge in this field.

5. Confidentiality

During your participation in this project, the principal investigator, co-investigators, and research staff will collect information about you in a research file that is necessary to meet the scientific objectives of this study.

This information may include data from your medical record concerning your past and present health status, lifestyle habits, and the results of all tests, examinations, and procedures performed. Your file may also include information such as your sex, age, and ethnic origin.

All collected information will remain confidential within the limits of the law. You will be identified only by a code number. The key linking your name to your research file will be kept in a locked filing cabinet and on a secure server.

For safety purposes, a copy of this consent form will be placed in your medical record. Therefore, any person or company to whom you grant access to your medical record will have access to this information.

Research data will be kept for 7 years by the principal investigator and will then be destroyed.

Research data may be published or discussed in scientific settings, but you will not be identifiable.

For purposes of monitoring, control, protection, and security, your research file and medical records may be consulted by representatives of the institution, the funding agency, or the Research Ethics Committee. These individuals are bound by confidentiality policies.

You have the right to consult your research file to verify the information collected and request corrections if necessary.

6. Compensation in case of injury

If you suffer any harm as a result of participating in this research project, you will receive all care and services required by your health condition.

By agreeing to participate in this research project, you do not waive any of your rights nor do you release the principal investigator, the funding agency, or the institution from their civil or professional liability.

7. Funding of the research project

This research project is funded by the Medtronic Chair in Spinal Trauma of the Université de Montréal, managed by Dr. Jean-Marc Mac-Thiong at Hôpital du Sacré-Cœur de Montréal, CIUSSS du Nord-de-l'Île-de-Montréal.

8 Voluntary participation and right to withdraw

Your participation in this research project is voluntary. You are therefore free to refuse to participate. You may also withdraw from the project at any time, without having to provide a reason, by informing the research team.

Your decision not to participate or to withdraw from this research project will have no impact on the quality of the care and services to which you are entitled or on your relationship with the teams providing them.

The principal investigator or the Research Ethics Committee may terminate your participation without your consent. This may occur if new findings or information indicate that continued participation is no longer in your best interest, if you do not follow the study instructions, if you do not consent to continue your participation after being informed of changes to the study that may affect you, if the study is discontinued, if continued participation becomes harmful to your health, or for administrative reasons.

If you withdraw from the project or are withdrawn from the project, the information already collected as part of this study will nonetheless be retained, analyzed, or used to ensure the integrity of the research project.

Any new knowledge acquired during the course of the study that may affect your decision to continue participating will be communicated to you promptly.

9. Compensation

You will not receive any financial compensation for your participation in this research project. Your participation in this study will not involve any costs to you.

10. Communication of results

You will not have access to your individual results.

If you wish to receive a written summary of the general study results, please provide an email address where we can send them to you:

12. Ethical oversight of the research project

The Research Ethics Committee of the CIUSSS du Nord-de-l'Île-de-Montréal has approved this project and will ensure its ongoing monitoring. In addition, it will review and approve in advance any revisions or modifications made to the information and consent form and to the research protocol.

You may contact the Research Ethics Committee at (514) 338-2222 ext. 3581.

CONSENT

Title of the research project:
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Participant Consent

I have read the information and consent form. The research project and this information and consent form have been explained to me. My questions have been answered and I was given sufficient time to make a decision. After reflection, I voluntarily agree to participate in this research project under the conditions described herein. I understand that I may withdraw from this study at any time.

A copy of the information and consent form will be placed in my medical record. Consequently, I understand that this information will be accessible to any person or company to whom I grant access to my medical record.

I authorize the research team to access my medical record.

I authorize the principal investigator of this research to contact me in order to ask whether I am interested in participating in other research studies.

Yes ❒ No ❒

A signed and dated copy of this information and consent form will be provided to the participant.

Participant's name [printed in block letters]	**Participant's signature**	Date [DD-MM-YYYY]

Signature of the person obtaining consent (if different from the principal investigator)
I have explained the research project and this information and consent form to the participant and have answered the questions he/she asked.

Name of the person obtaining consent (printed in block letters)	Signature	Date [DD-MM-YYYY]

Signature and commitment of the principal investigator

I certify that the participant was informed of this information and consent form, that all of his/her questions were answered, and that it was clearly explained that participation is voluntary and that he/she remains free to withdraw at any time without prejudice. I undertake, together with the research team, to respect what has been agreed upon in the information and consent form and to provide the participant with a signed and dated **copy.**

Name of the principal investigator [printed in block letters]	Signature	Date [DD-MM-YYYY]