Study Protocol

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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I. Introduction

Early mobilization is safe and feasible in critically ill patients (1–6), as well as in patients who have undergone spinal surgery (7, 8). However, despite strong evidence of the benefits of early mobilization after surgery, few patients actually mobilize early (1, 7–9).

The literature shows that more than 57% of patients of all ages and 83% of patients over 65 years old remain in bed for most of their hospital stay (10). In our institution, this prolongs the length of hospital stay and reduces the rate of discharge home by 20%. Faced with this harmful and reversible epidemic, no sustainable solution has yet been proposed for rapid and effective mobilization of patients after spinal surgery. Indeed, the solutions proposed so far involve getting the patient out of bed. Thus, a patient without surgical complications still needs an intermediate step to help them realize that they are capable of mobilizing independently. In-bed mobilization using a bedside cycle, which has already proven effective in critically ill patients (11, 12), appears very promising for these patients. However, no study has yet evaluated this approach. Our study therefore aims to demonstrate the effectiveness of this mode of mobilization.

II. Problem Statement

The issue of the mode of patient mobilization has been poorly studied. A few authors have examined it without identifying an effective and sustainable solution (8).

There is no clear consensus regarding the method of mobilization after spinal surgery. To date, each center and care team adopts its own approach. Some mobilize patients through physiotherapy, while others follow a protocol consisting of a sequence of exercises that the patient must perform during hospitalization (6, 8, 13). In our institution, patients after elective spinal surgery may mobilize according to their tolerance unless there is a contraindication secondary to a surgical complication, such as cerebrospinal fluid leakage or residual instability. Limited human resources in physiotherapy mean that patients do not immediately receive physiotherapy, and most patients for whom physiotherapy is recommended receive a functional assessment and treatment only on postoperative day 2 or 3. The functional assessment determines whether the patient can be discharged home or requires intensive functional rehabilitation. This entire process often causes delays in mobilization.

The impact of this delay is significant and harmful. The population undergoing spinal surgery is increasingly older (8). These patients are prone to deconditioning related to immobilization and associated complications (pneumonia, atelectasis, constipation, venous thrombosis, etc.) (10, 14–16). It is therefore important to mobilize these patients rapidly during hospitalization using a simple and acceptable method in order to reduce length of stay and promote discharge home.

Thus, there is a critical need in our center to better structure early mobilization after spinal surgery. This would facilitate patient engagement while ensuring safety and modifying staffing requirements. In-bed cycling has the potential to meet this need. In other fields, it has already demonstrated significant benefits.

III. Literature Review

The alarm regarding the epidemic of time spent in bed during hospitalization was raised long ago. Indeed, alarming statistics show that hospitalized patients spend more than half of their time in bed without a specific reason (2, 4). Mudge et al. demonstrated that patients of all categories combined (medicine, surgery, oncology) spend 57% of their hospital stay lying in bed and only 9% standing or walking (16). In elderly patients, this phenomenon is even more pronounced: 83% of their time is spent in bed and only 3% walking (10). Over 24 hours, these patients spent 20 hours in bed and only 43 minutes walking.

These authors highlight barriers to mobilization. In addition to the lack of physiotherapists, they agree that the main barriers fall within the "knowledge-to-practice gap," reflecting insufficient knowledge about early mobilization (1, 4). Patients believe that during hospitalization they must remain in bed or be mobilized only by physiotherapy (4). In Anekwe et al.'s study, 49% of intensive care staff considered early mobilization to be a low priority during hospitalization (1). In this Montreal study (1), 63% of nursing staff incorrectly feared that mobilization would lead to dislodgement of lines and catheters.

Pain was presented as a major limiting factor for mobilization (6, 10). However, since the introduction of effective postoperative analgesia, patients still do not mobilize more. Early mobilization may even provide benefits by reducing long-term pain and opioid use (17, 18).

In spinal surgery, concerns about the safety and feasibility of early mobilization have been refuted by the literature (6–8, 13, 14, 17–21). The risk of accidental removal of lines and catheters is reported to be 1% in Leditschke's study (5). Rupich suggests that it is safe to mobilize patients as early as 6 hours postoperatively for spinal surgeries without fusion (6). Nielsen et al. introduced a protocol involving 30 minutes of walking within 24 hours postoperatively. With this protocol, patients gained confidence in getting up and were able to perform daily activities in hospital (getting out of bed, going to the toilet, moving to eat). However, large-scale implementation of this protocol is not possible due to physiotherapy staffing limitations and patient-related difficulties (17, 21).

Early mobilization promotes functional maintenance and thus reduces length of hospital stay (8). Immobilization promotes deconditioning (losses in biopsychosocial functioning) and complications, particularly in older populations (14, 17). Loss of functional capacity related to immobilization increases length of stay and the need for intensive physiotherapy care (8). According to local statistics developed by the physiotherapy team, 20% of patients assessed cannot return home and require intensive acute therapy. In a geriatric population, early mobilization after lumbar fusion improves discharge home rates from 64% to 75% (19). Early

postoperative mobilization prevents deconditioning and reduces physiotherapy needs (6, 14, 21). Thus, the patient becomes more autonomous and mobilizes more frequently. Walking within 24 hours after surgery has been shown to reduce the incidence of complications such as hematomas and surgical site infections (9, 14). However, the full potential of early mobilization to reduce length of stay has not yet been achieved due to the lack of an effective and sustainable mobilization method.

In-bed mobilization offers notable potential for mobilizing patients after spinal surgery. Kho's team demonstrated that bedside cycling is feasible and safe in critically ill patients (11) and in mechanically ventilated patients (12). This mobilization method does not require moving the patient and helps overcome barriers faced by the medical team. For the patient, cycling in bed allows them to realize that they are capable of mobilizing independently, unless medically contraindicated, and that they do not need to wait for physiotherapy. It provides a reassuring intermediate step between bed rest and the demanding task of standing and walking. Although this mode of mobilization has existed for several years (22), its effectiveness has not yet been demonstrated in patients after elective spinal surgery.

IV. Objectives and Hypotheses

a. Primary objective

The primary objective of this study is to demonstrate the effectiveness of early mobilization by in-bed cycling on the day after elective spinal surgery. Effectiveness will be reflected by a reduction in the time spent in bed compared with patients who do not use the cycle and receive standard care.

b. Hypothesis

Early mobilization by in-bed cycling reduces the amount of time the patient spends in bed over a 24-hour period.

c. Primary outcome

Early mobilization using in-bed cycling sessions the day after spinal surgery reduces by 1 hour and 30 minutes the time patients spend in bed starting on postoperative day 2. In the literature, patients spend on average 17 hours out of 24 in bed. In Pedersen's study, the same patient spent 1 hour and 30 minutes less time in bed on days when they had full mobility compared with days when their mobility was reduced (23).

a. Secondary objectives

Secondary objectives are to measure length of hospital stay, kinesiophobia, and mobility in patients who completed a cycling session. These outcomes will be compared with patients who did not receive cycling sessions.

b. Secondary outcomes

1. Early mobilization by in-bed cycling allows faster discharge home by reducing length of hospital stay in days.
2. Early mobilization by in-bed cycling starting the day after spinal surgery allows faster improvement in functional capacity, as measured by validated questionnaires (24) and functional tests (25).
3. Early mobilization by in-bed cycling improves patient participation during physiotherapy assessment sessions. This improvement is rated by the therapist using the Pittsburgh Rehabilitation Participation Scale. According to Lenze (26), patient participation during acute rehabilitation sessions is correlated with the Functional Independence Measure score. Participation reflects functional capacity.

V. Methodology

5.1 Study design

This project is a prospective, single-blind randomized clinical trial lasting one year. Participants meeting inclusion criteria are enrolled and remain in the study until postoperative day 2. No follow-up is planned afterward.

In accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) and to facilitate future publication in peer-reviewed journals, this clinical trial will be registered on ClinicalTrials.gov.

Randomization and data analysis are conducted independently to allow blinded analysis. Due to the interventional nature of the study, personnel delivering the intervention are different from those analyzing the data to maintain single blinding. The person responsible for data analysis has no access to group allocation.

5.2 Sample size

Based on Pedersen's study, a patient with reduced mobility spends 17 hours out of 24 in bed. When the same patient is independent in basic mobility, this time is reduced by 1.6 hours, resulting in 15.4 hours spent in bed. The reported standard deviation for time spent in bed is 12%, or 2.1 hours (10, 23). Using these data and setting study power at 90%, the minimum required sample size is 76 participants. To account for potential exclusions due to postoperative complications or post-randomization exclusions, we increased the sample size by 15%. The final sample size is therefore 88 participants, divided into two groups (control and intervention) of 44 participants each. The sample size was calculated using G*Power 3.1.9.2.

5.3 Study population and eligibility

The groups will consist of patients in the immediate postoperative period following elective spinal surgery who have not experienced complications.

Table 1: Study eligibility and inclusion

Inclusion criteria
Female or male aged ≥ 18 years. Postoperative day 0 following elective spinal surgery of the decompression type with or without fusion, or fusion. Patient able to walk independently before surgery (not dependent on another person for ambulation and not using a wheelchair). Patient admitted directly from the operating room to the ward. Hemodynamically stable patient: compared with baseline values or with the parameters below: o Systolic blood pressure (SBP): ≥ 90 mmHg and < 140 mmHg. o Oxygen saturation > 94%. o Heart rate (HR): 50–100 bpm. Patient cleared for surgery following evaluation by internal medicine in the preoperative clinic. Alert and conscious patient. Valid informed consent obtained from the participant.

Table 2: Exclusion criteria at recruitment and justification

Exclusion criteria	**Justification**
Non-ambulatory preoperatively.	The study evaluates mobilization after surgery. By design, the participant must be independent in walking.
Body mass index (BMI) > 40 kg/m².	Morbid obesity is associated with major limitations in performing in-bed cycling due to ergonomic and positioning issues. It also limits hip range of motion. In addition, the cycle supports a maximum weight of 100 kg.

Spinal trauma with acute neurological deficit.	Spinal trauma with neurological impairment causes spinal instability and motor function loss, which prevents mobilization and makes the participant non-independent in walking.
Preoperative non-neurological lower-limb impairment: musculoskeletal deformity, amputation, hip fracture, severe osteoarthritis preventing full joint range of motion, etc.	In-bed cycling is contraindicated due to feasibility concerns.

Patient with comorbidities assessed by internal medicine and not cleared for surgery. Special attention is given to the following comorbidities: cardiovascular, respiratory, diabetes.	All patients are assessed by internal medicine before surgery. If internal medicine determines that the patient is unfit for surgery, the patient is excluded from the study. Criteria for elective surgery are the same as for cycling: risks must not outweigh benefits. Absence of cardiovascular, respiratory, and metabolic instability is required.
	
	Special attention is given to the following comorbidities:
	
	• Cardiovascular:
	  ○ Heart failure
	  ○ Increased cardiovascular event risk (myocardial infarction [MI], unstable angina, arrhythmia, moderate or severe aortic stenosis, cerebrovascular accident [CVA])
	  ○ MI, arrhythmia, CVA, acute thrombophlebitis, recent pulmonary embolism
	  ○ Orthostatic hypotension
	  ○ Arterial hypertension
	  ○ Anemia
	• Respiratory: COPD
	
	Diabetes

Expected length of stay < 2 days after surgery.	Total participation lasts 2 days; therefore, patients with an expected hospital stay of less than 2 days are not enrolled.

Table 3: Exclusion criteria after recruitment but before randomization

Exclusion criteria	Justification
Surgical complications (e.g., acute neurological deficit, dural tear, cerebrospinal fluid leak, residual spinal instability).	Strict bed rest ordered by the care team.
Concern from the medical team (including the research team) regarding imminent arrhythmia or myocardial infarction.	Participation presents excessive potential risk.
Patient in or transferred through the intensive care unit.	ICU patients have hemodynamic instability or frailty, increasing potential risks.
Hemodynamic instability before the session: SBP < 90 mmHg or > 200 mmHg; oxygen saturation < 88%; HR < 50 or > 100 bpm; temperature > 38 °C.	If instability persists despite attempts at medical stabilization, the patient is excluded for safety reasons.
Capillary blood glucose outside target values: < 4.0 or > 7.0 mmol/L fasting or before meals; < 5.0 or > 10.0 mmol/L 2 hours after meals.	Participation presents excessive potential risk.
Patient confused, disoriented, or agitated at the time of intervention.	Invalidates informed consent.
Patient already evaluated by physiotherapy.	Physiotherapy determines discharge destination and initiates interventions; the patient is no longer available for the study.
Patient in isolation.	Participation presents excessive potential risk and equipment sterilization is difficult.
Patient already discharged.	No follow-up is planned; patient is no longer available for the study.

Study procedure and assessments

6.1 Participant recruitment: consent

Hôpital du Sacré-Cœur de Montréal (HSCM) is a referral center for spinal surgery. With both neurosurgical and orthopedic spine teams, an average of 30 patients per month undergo elective surgery for spinal conditions. With an acceptance rate of approximately 80%, we aim to recruit 24 patients per month.

Patients operated on by Drs. Mac-Thiong, Pelletier-Roy, Laroche, and Khoueir will be approached for recruitment after approval by the research ethics and scientific committees.

Once authorization is obtained from each surgeon, the research team will have access to surgical schedules and will identify potentially eligible patients through chart review.

Any patient scheduled for spinal surgery (cervical, thoracic, lumbar, or sacral) involving decompression with or without fusion, or fusion, with an expected hospitalization longer than two days, will be approached preoperatively—either in the preoperative internal medicine clinic or during a visit with the surgeon. Patients who walk independently (do not require assistance and do not use a wheelchair) are eligible.

A research team member will present the project, explain the objectives, hypothesis, and outcomes.

After confirming understanding and answering questions, the researcher administers a screening questionnaire covering inclusion and exclusion criteria (including cardiovascular comorbidities such as severe heart failure, recent myocardial infarction, uncontrolled arrhythmia). If the patient meets inclusion criteria, informed consent is obtained. The information and consent form (ICF) has been reviewed by the Research Ethics Committee and complies with Good Clinical Practice and local regulations. Patients are informed they may withdraw at any time.

Participants then complete questionnaires assessing walking ability and functional independence (Functional Independence Measure [27], SF-36 Quality of Life [28], and SCIM [29]).

The researcher records sociodemographic data (age, height, weight, ethnicity) and medical history.

6.2 Randomization

A list of participants to be randomized is created after consent is obtained. Immediately after surgery, the research staff visit selected participants in their hospital rooms to confirm participation and ensure no postoperative exclusion criteria are present. Randomization can then proceed, reducing selection bias between groups.

Randomization occurs the day after surgery and is performed by the study biostatistician, who has no contact with participants and does not know their identities. Confidentiality is ensured through coding prior to randomization. The key linking participant names to study files is stored securely in a locked cabinet and on a secure server.

Randomization envelopes are generated using a computer-based random number set with a 1:1 allocation ratio. The allocation formula is as follows: the first participant is randomized to one of the two groups; the next participant is assigned to the opposite group.

On the day of surgery, research staff visit all participants postoperatively to confirm eligibility and collect surgical data (baseline pathology, type of surgery, absence of complications, vital signs). Each participant receives a Fitbit Inspire HR, to be worn on the left wrist at all times until postoperative day 2.

On postoperative day 1, kinesiophobia is assessed using the validated Canadian French version of the Tampa Scale for Kinesiophobia (TSK-FC). The Five-Repetition Sit-to-Stand Test is administered after the cycling intervention. All participants receive standard care at HSCM: assisted transfer out of bed into a chair the day after surgery.

On postoperative day 2, the research staff evaluate all participants (control and intervention groups) for:

1. pain, mobility, and kinesiophobia;
2. postoperative complications;
3. removal of the watch.
   This concludes the intervention.

Physiotherapy functional evaluation is conducted independently of the study and is based on the patient's ability to get out of bed, transfer, and ambulate, determining discharge destination. Physiotherapists are blinded to the intervention.

7.1 Control group

Participants receive the watch and standard care at HSCM. Mobilization over 24 hours is assessed on postoperative day 1. Kinesiophobia (TSK-FC) and mobility are assessed on postoperative days 1 and 2.

7.2 Intervention group

The intervention consists of a 30-minute in-bed cycling session on the day following surgery.

On postoperative day 1, a research team member visits the patient several hours before cycling to administer kinesiophobia (Tampa Scale for Kinesiophobia) and pain (VAS) questionnaires. Two research staff then conduct the cycling session, ensuring hemodynamic and neurological stability. Pain is assessed using the 10-point Visual Analog Scale (VAS), and type and amount of analgesics are recorded. The procedure is explained and participants are instructed to report any discomfort.

The head of the bed is elevated to approximately 30°, ensuring ergonomic positioning. A blood pressure cuff is placed on the right arm (or opposite the watch), and a pulse oximeter is placed on the left hand (or same side as the watch). Capillary glucose is measured in diabetic participants.

Vital signs (HR, BP, SpO_2) are monitored continuously; BP is recorded at 0, 1, 3, and 5 minutes, then every 5 minutes. A trained researcher remains with the participant throughout the session, monitoring physiological parameters and comfort. Pain and dyspnea are assessed at 10 and 20 minutes and as needed. Early stopping criteria allow the session to be stopped at any time.

Assistance mode on the ergometer may be used to achieve the target cadence of 40 RPM, which corresponds to a walking cadence of approximately 80 steps/min in healthy individuals. Participants aim to maintain this speed for 20 minutes, followed by a 5-minute cool-down. Speed is visually monitored and adjusted.

If the participant cannot maintain cadence in active mode, active-assisted mode is used.

At 30 minutes, vital signs and glucose (if needed) are reassessed, and pain is evaluated. Measures are taken if pain is elevated. A 24-hour mobility assessment then begins using the watch.

Several hours after cycling, mobility is assessed using the Five-Repetition Sit-to-Stand Test, and kinesiophobia and pain questionnaires are completed. These assessments are repeated on postoperative day 2.

7.3 Safety parameters

Stopping criteria are established to allow either the participant or the supervising staff member to terminate the session early (11, 22). These criteria are based on previous studies conducted in critically ill patients and have been adapted for this study. Monitoring of these parameters is carried out in collaboration with the participant.

• Abnormal vital signs

- Persistent oxygen desaturation < 94%
    - Or a persistent drop in saturation of 4%
- Heart rate > 200 bpm or paradoxically < 40 bpm
- Blood pressure:
    - Increase in systolic blood pressure (SBP) > 20 mmHg or mean arterial pressure (MAP) > 110 mmHg
    - Or decrease in SBP > 20 mmHg (suggestive of cardiac failure)

• Pain reported by the participant or discomfort. Signs and symptoms of exercise intolerance

- Modified Borg scale > 8
- Chest, epigastric, back, or arm pain: angina
- Shortness of breath or dyspnea disproportionate to the level of effort
    - At any time, if the patient reports shortness of breath causing them to slow down, motor assistance will be increased until dyspnea resolves
    - If shortness of breath persists, the session will be terminated
- Severe joint pain
- Dizziness and vertigo: pallor, cyanosis, nausea, sudden sweating, fatigue, leg cramps
- Palpitations
- Headache

• Patient becomes agitated during the session
• Dislodgement of equipment: cycle, board, catheter
• Request by the participant to stop

7.4 Equipment and storage

A smartwatch with integrated pedometer and accelerometer ("Fitbit Inspire HR fitness trackers" or "Fitbit Inspire 2 fitness trackers") with heart rate monitoring will be assigned to each participant to track mobilization.

This watch specifically measures the number of steps over 24 hours, distance traveled, calories burned, total activity time, sleep time, time spent lying in bed, etc. It distinguishes time spent stationary from time spent walking. Regarding vital signs, it provides heart rate data.

Four watches will be used for the project. They will be stored in our facilities in room C2080.

The removable wristband and the watch face will be cleaned before and after each use with the same disinfecting agents used in the operating room between cases for sterilizing equipment such as operating tables.

The watch has a data storage capacity of seven days. After retrieval, it will be connected to a compatible computer to download the data. Data collected by the watch before, during, and after the intervention will be stored in three separate files.

- Data before the intervention will be used to verify hemodynamic stability and will be correlated with nursing vital signs; these data will not be used for analysis.
- Data related to the intervention are collected to ensure hemodynamic stability and are not part of the primary outcome analysis. They are stored separately to maintain blinding during data analysis.

In-bed leg cycling consists of daily 30-minute sessions using an SF-B0717 ergometer or an APT5 ergometer. Since both devices have identical measurement parameters, they may be used simultaneously to provide cycling sessions for all enrolled patients and to avoid interruptions due to equipment failure.

A portable ergometer (SF-B0717 Electric Surface Cycle 90 or APT5) will be used for in-bed cycling. This device allows different pedaling modes according to participant ability:

- Active-assisted mode: pedaling assisted by the motor
- Active mode: pedaling entirely driven by the participant

The motorized ergometer has 12 speed levels ranging from 30 to 90 RPM (in increments of 5). A remote control allows adjustment of direction, speed, and start of the device. It includes a timer for time tracking. The maximum supported weight is 100 kg.

To install the ergometer in bed, an adjustable table for tabletop ergometers (model ERP7957-01) will be used. This table can be adjusted according to participant height and bed height to achieve a 30° head-of-bed angle and appropriate ergonomic positioning. The cycle and table will be stored in room C2080.

A motorized portable ergometer (APT5 Active Passive Trainer on Hi-Low Stand, ORTHOCANADA) will also be used. The APT5 can be adjusted in length and includes an adjustable crank and leg support to ensure stability and proper alignment of the lower limbs during pedaling.

The system includes a display screen showing cycling parameters such as cadence and power output. The APT5 screen is used to program cycling mode, cadence, time, power, and speed level. As with the SF-B0717, three cycling modes are available:

- Passive (motor-driven without patient initiation)
- Active-assisted (partially initiated by the patient with motor assistance)
- Active (fully initiated by the patient)

Cycling mode and motor speed can be adjusted to achieve the desired cadence.

When not in use, the system will be stored in the physical department of our institution.

Before and after each use, the pedaling devices and the SF-B0717 support will be sterilized using the same disinfecting agents used in the operating room between cases for equipment such as operating tables.

For monitoring vital signs, a blood pressure cuff and a digital pulse oximeter will be placed on the participant during the intervention.

VIII. Data collection and analysis

Confidentiality is ensured for all participants through a coding system. Each participant will receive a code. The key linking the participant's name to the research file will be kept in a locked cabinet and on a secure server.

For both primary and secondary outcomes, data are collected before and after the intervention.

Data collection and storage will be performed using Excel.

The main document will contain all data required for analysis of the primary outcome, except those identifying group allocation, i.e., all data collected during the intervention (questionnaire and test scores, vital signs, VAS scores). These will be stored in a separate file.

8.1 Data collected

Before the intervention, at the time of consent, the research staff administer a questionnaire on walking ability and functional independence (Functional Independence Measure [FIM], SCIM, and SF-36). Modified versions of the FIM, SCIM, and SF-36 are used for study purposes.

- With the modified SF-36 ("limitations in activities" section), limitations in activities of daily living (ADLs) are assessed.
- With the modified FIM ("locomotion" and "transfers" sections), locomotion and transfer abilities in ADLs are specifically evaluated.
- With the modified SCIM ("Mobility indoors and outdoors on level surfaces" section), the level of assistance required for ambulation is specifically assessed.

These measures will be used in data analysis, as baseline performance is expected to influence the primary outcome (time spent out of bed). The researcher also collects sociodemographic data (age, height, weight, ethnicity) and medical history.

If the participant cannot maintain the target speed of 40 RPM, they may continue the intervention at a lower comfortable speed. This will be recorded and taken into account in data analysis. The same applies to pedaling duration.

Table A: Baseline characteristics of the study population

	Variable	**Type of categorization**
ID	Last name	
	First name	
	Medical record number	
	Date of birth	
	Identification code	
Sociodemographic	Age	Continuous
	Sex	Dichotomous
	Marital status	Categorical
	Race	Categorical
	Weight	Continuous
	Height	Continuous
	BMI	Continuous
Comorbidities		Will be recorded
Surgery-related data	Underlying pathology	Will be recorded
	Type of surgery	Categorical
	Date of surgery	Continuous
	Complications	Will be recorded
	Surgical team (neurosurgery vs orthopedics)	Dichotomous
	Analgesia (type)	
	Analgesia (amount taken before the intervention)	

	Analgesia (amount taken after the intervention, assessed on POD#2)	

Table B: Primary outcomes

	Variable	**Type of categorization**
Mobility	Basic mobility (1: without assistance, 2: with assistance, specify, 3: non-ambulatory)	Categorical
	FIM score	Continuous
	SF-36 score	Continuous
	SCIM score	Continuous
	Tampa Scale for Kinesiophobia score (TSK-FC)	Continuous
	Time for five repetitions of sit-to-stand	Continuous
Intervention-related data	Group allocation	
	Pain level (immediately before, during, and immediately after)	Dichotomous
	Vital signs before, during, and after intervention (HR, BP, SpO_2)	Continuous
Fitbit data over 24 hours	Active minutes	Continuous
	Walking time	
	Number of steps	Continuous
	Calories burned	Continuous
	Sleep time	Continuous
	Time spent in bed	Continuous

Table C: Secondary outcomes

	Variable	**Type of categorization**
Hospitalization-related data	Patient out of bed on postoperative day 1	Dichotomous
	Hospitalization-related complications	Will be recorded
	Length of hospital stay	Continuous
	Discharge destination (inpatient rehabilitation unit [URFI] vs home discharge [RAD])	Dichotomous
Pittsburgh Rehabilitation Participation Scale score		Categorical

8.2 Statistical analysis plan and data analysis

All statistical analyses will be performed by a statistician blinded to participant identity and group allocation. The statistician will have no contact with participants.

No loss to follow-up is expected, as there is no follow-up period. In the event of premature termination, data collected prior to withdrawal will be used, and mobilization will be assessed over the subsequent 24 hours. Statistical power to detect a statistically significant difference is set at 80%, with a type I error rate (alpha) of 0.05.

8.2.1 Primary outcome analysis

Data will be analyzed and reported according to the intention-to-treat principle. In addition to descriptive statistics, comparisons between the intervention and control cohorts will be performed using Student's t-test. Given that randomization is expected to reduce confounding, we do not anticipate adjusting for other potential confounders (age, sex, type of surgery) in the primary analysis. However, baseline characteristics between the intervention and control groups will be compared using multivariate analysis, and adjustments will be made for any confounders that differ substantially between groups.

The primary outcome is defined as the amount of time the participant spends out of bed. These data will be obtained from the smartwatch.

8.2.2 Interim analysis

A micro-analysis of the data will be conducted after the inclusion of 30 participants (15 per group). The objective of this interim analysis is to assess the safety of the intervention. Early mobilization following spinal surgery has been shown to be safe in the literature. Similarly, the use of in-bed cycling has been demonstrated to be safe in mechanically ventilated ICU patients receiving vasopressors. However, no study to date has evaluated the use of in-bed cycling as a mobilization strategy following spinal surgery, which highlights the innovative nature of this project. This interim analysis will also allow for reassessment of the study objectives.

8.2.3 Secondary outcome analysis

To determine the impact of mobilization on hospitalization and functional capacity, three secondary outcomes have been defined.

The first evaluates the effect of early mobilization through in-bed cycling on length of hospital stay.

The second evaluates patient mobility using the five-times sit-to-stand test and the TSK-FC questionnaire.
The third evaluates the effect of the intervention on patient participation in physiotherapy assessment sessions. This outcome is measured using the Pittsburgh Rehabilitation Participation Scale. This scale has been validated in the literature and is correlated with the Functional Independence Measure (FIM). It has been shown to reflect patients' functional capacity.

All secondary outcome analyses will be performed using Student's t-test.

IX. Ethical considerations

Following approval by the Research Ethics Committee, all patients scheduled for spinal surgery will be approached preoperatively, either during their preoperative visit with the physician or on the day of surgery, in order to obtain informed consent. After providing free and informed consent, each patient will be randomized to one of the study groups.

Participants are free to withdraw their consent at any time during the study. Prior to the intervention, they may choose not to complete the cycling session. After the session, they may request that their data be withdrawn from the study.

X. Relevance and expected impact

Hospitalization-related costs are substantial. At our institution, the cost of one day of hospitalization is approximately CAD $3,267, excluding professional fees. According to the literature, a simple early mobilization intervention may reduce these costs by decreasing length of stay and complications related to deconditioning. An increase in the amount of time patients spend out of bed reflects improved functional capacity. Physiotherapy assessments will therefore more frequently and earlier identify patients as suitable for discharge home.

With the introduction of in-bed cycling sessions beginning the day after elective spinal surgery, a reduction in length of hospital stay and associated costs is expected.

The quality and simplicity of the mobilization protocol will reduce the human resources required for patient mobilization. In neurologically intact patients, only a single nursing staff member will be required for supervision. This approach also helps address physiotherapist workforce shortages.

In-bed cycling provides significant potential benefits for patients. Early mobilization has been associated with increased patient satisfaction with hospitalization.

XI. Dissemination of results

Study results will be disseminated through publications accessible to the general public. Participants in the study will also be given the opportunity to consult these articles after publication.

XII. Timeline

Study duration: 2 year

Initial protocol:

- Review by the Research Ethics Committee (REC): December 2019 – April 2020
- Approval by the REC and Scientific Committee: April 2020
- Participant recruitment, randomization, and intervention: April–June 2020
- Statistical analysis: June–July 2020
- Dissemination of results: August 2020
- Submission for peer review: September 2020

After protocol modification:

- Approval by the REC and Scientific Committee: February 2026
- Participant recruitment, randomization, and intervention: March–August 2028
- Statistical analysis: August 2028
- Dissemination of results: January 2029
- Submission for peer review: January 2029

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