

Informed Consent Form for Participation in a Research Study

Study Title: CYCLE RCT: An international, multi-centre, randomized clinical trial of early in-bed cycling for mechanically ventilated patients

Principal Investigator:

Dr. Michelle Kho, PT, PhD
Physiotherapy Department, St. Joseph's Healthcare
School of Rehabilitation Science, McMaster University
Hamilton, ON

Office: 905-522-1155 Ext. 32223
Cell: 289-237-0194

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INTRODUCTION

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end. Throughout this form, "you" means the person you are representing.

You are being invited to participate in a clinical trial (a type of study that involves research) because you have been admitted to the Intensive Care Unit (ICU), require a breathing machine, and are expected to be in the ICU for another 2 days or more. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care.

IS THERE A CONFLICT OF INTEREST?

Two centers in this study received a load of in-bed cycles from Restorative Therapies, the equipment manufacturer, who has no influence on the design, analysis, or publication of this trial.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Patients in the ICU are the sickest in the hospital. Even after they recover, these patients are very vulnerable to disability. Up to 1 in 4 patients have severe leg weakness that reduces their quality of life for as long as 5 years after ICU discharge. In-bed cycling uses equipment that attaches to a hospital bed, allowing gentle leg exercise for patients in the ICU. In one study, patients who received physiotherapy and in-bed cycling after 2 weeks in the ICU could walk farther at hospital discharge than those who received physiotherapy alone. In our study, we will offer in-bed cycling to patients who need a breathing machine to help them recover from weakness as fast as possible. After completing studies to ensure that patients and their families are interested in participating, and that in-bed cycling in the ICU is safe, we are ready to test whether in-bed cycling reduces disability.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out whether patients who receive in-bed cycling plus routine physiotherapy have better physical function than patients who receive routine physiotherapy only.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. Physiotherapy is commonly administered to patients who are on a breathing machine in the ICU. Even if you do not participate in this study, you will still receive the standard of care as determined by your treatment team in the ICU.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 360 people will take part in this study, from research sites located in Canada, Australia, the United States of America, and Brazil. This study should take about 3 years to complete and the results should be known in about 5 years.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to participate then you will be “randomized” into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you, nor the study staff, can choose what group you will be in. Once you are randomized, you will be told which group you are in.

WHAT IS THE STUDY INTERVENTION?

Group 1 (Experimental Intervention): In-bed cycling plus routine physiotherapy

If you are randomized to this group you will receive 30 minutes of in-bed cycling once per day, 5 days per week while you are in the ICU, up to a maximum of 28 days. The study physiotherapist will place your legs in the in-bed cycle. The in-bed cycle will allow you to cycle on your own or will help you cycle with a gentle motor. You will also receive routine physiotherapy as described below.

Group 2 (Non-Experimental Intervention): Routine physiotherapy only

If you are randomized to this group you will receive routine physiotherapy which includes exercises to keep your arms and legs moving and strong, and activities to help you with sitting, standing, and walking as you are able. It may also involve techniques to help you breathe more easily and help to keep your lungs clear if needed.

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION?

Every week day your physiotherapist will check to make sure you are medically well enough to receive the intervention. During all sessions, the physiotherapist will carefully monitor your progress. If you have specific signs or symptoms of distress, the session will be stopped. You may also choose not to participate in any study session on any particular day should you feel unwell or uncomfortable.

WHAT ARE THE STUDY PROCEDURES?

If you volunteer to participate in this study, we will first get medical information from your hospital records and/or by speaking with you or your close contacts (e.g., personal health information, physical measurements, test results, etc.).

You will also be asked to complete several strength and functional tests at the following times during your hospital stay: in the ICU, after you leave the ICU, and just before you leave the hospital. During the strength tests, we will ask you to move your arms and legs against resistance from our hands. During the functional tests, we will ask you to perform certain movements if you are able, such as standing up, marching on the spot, and walking. We will ask you some questions about how you feel you are doing with your health and mobility. These tests will take less than an hour and should be painless.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Receive the treatment (in-bed cycling and routine physiotherapy or routine physiotherapy alone)
- Complete strength and functional tests as best as you can
- Answer questions about your health

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention will last for a maximum of 28 days in the ICU. Strength and function testing as described above will be done when you wake up in the ICU, when you are transferred out of the ICU, 3 days after you are

transferred out of the ICU, and when you are ready to leave the hospital. Approximately 3 months after you were enrolled in the study, we will contact you to ask you questions about your health.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the study staff know. However, this would also mean that you withdraw from the study. Information that was recorded before you withdrew will be used by the researchers for the purposes of the study. If you withdraw from the study, we will request your permission to record further information related to the safety of the study only. This information will be collected from your medical record and will require no further action on your part, but it will help us to make sure that the study is safe for other participants.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study staff may stop your participation in the study early, and without your consent, for reasons such as:

- You are unable to tolerate the study intervention
- New information shows that the study intervention is no longer in your best interest
- The study sponsor decides to stop the study
- The research ethics board withdraws permission for this study to continue

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. The investigator will tell you why, and you will continue to be cared for outside of the study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. You should discuss these with the study staff. The study staff and your medical team will watch you closely to see if you have side effects.

Risks and side effects related to in-bed cycling are rare. Most patients have no problems or discomfort. However, you may be at risk of feeling tired or you may experience a slight increase in heart rate, breathing rate, or blood pressure from participating in this study. Accidental removal of intravenous lines or tubes during an in-bed cycling session is possible, but the risk is very low (i.e., 0.2% of sessions). Rupture of the Achilles tendon (the tendon at the back of the leg that connects the calf muscle to the heel) is also possible, but is *very* rare (i.e., 0.1% of patients).

The risks and side effects of routine physiotherapy will be explained to you as part of your standard care. These risks are not included in this consent form.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you. It is possible you may have improved leg strength at hospital discharge following participation in this study. As the Canadian population ages, the number of people who will experience weakness following an ICU stay will increase dramatically. We hope the information learned from this study will help other people who need breathing machines in the ICU to regain strength and recover as quickly as possible in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study. Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines. Your study data may also be sent to the organizations listed below:

- The research ethics board who oversees the ethical conduct of this study in Ontario
- St. Joseph's Healthcare Hamilton, to oversee the ethical conduct of research at this location

Representatives of Clinical Trials Ontario may see study data that are sent to the research ethics board but your name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain "indirect identifiers" only (e.g. participant code, age, gender).

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/presented to the scientific community at meetings and in journals. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>. This website will not include information that can identify you. You can search this website at any time.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study. In the case of research-related side effects or injury, full medical care will be provided as usual.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to participating in this study. You have the right to be informed of the results of this study once the entire study is complete. The results of this study will be available on the clinical trial registry (see the "Will information about this study be available online" section for more details).

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form you do not give up any of your legal rights against the study staff or involved institutions for compensation, nor does this form relieve the study staff or their agents of their legal and professional responsibilities. You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the investigator who is in charge of the study at this institution. That person is:

<u>Dr. Michelle Kho</u>	<u>905-522-1155 Ext. 32223</u>
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

<u>Chair, Hamilton Integrated Research Ethics Board</u>	<u>905-521-2100 ext. 42013</u>
Name	Telephone

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to my medical records as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree, or agree to allow the person I am responsible for, to take part in this study.
- I will receive a signed copy of this form

_____ Signature of Participant/ Substitute Decision-Maker	_____ PRINTED NAME	_____ Date
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CONSENT TO FUTURE DATA LINKAGE

I agree to allow researchers to link my Ontario Health Insurance Plan (OHIP) number for future studies on my medical activities (e.g., hospitalizations, doctors' visits) and costs. I understand the researchers will use a de-identified encrypted version of my OHIP number to analyze data as available at the Institute for Clinical Evaluative Science, for the time spanning the 5 years before and after study entry.

_____ Signature of Participant/ Substitute Decision-Maker	_____ PRINTED NAME	_____ Date
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_____ Signature of Person Conducting the Consent Discussion	_____ PRINTED NAME & ROLE	_____ Date
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Complete the following section only if the participant is unable to read or requires an oral translation:

- The informed consent form was accurately explained to, and apparently understood by, the participant/substitute decision maker, and
- Informed consent was freely given by the participant/substitute decision maker

_____ Signature of Impartial Witness/Translator	_____ PRINTED NAME	_____ Date
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(If participant were unable to read/required an oral translation)

Version date of this form: April 04, 2018