Official Title: Implementing cycling as a mobility option for operative and non-operative patients with small bowel obstruction and ileus admitted by Northeast Acute Care Surgery at Atrium Health Cabarrus

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Implementing cycling as a mobility option for operative and non-operative patients with small bowel obstruction and ileus admitted by Northeast Acute Care Surgery at Atrium Health Cabarrus.

Informed Consent Form to Participate in Research

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1. SUMMARY

You are invited to participate in a research study. The purpose of this research study is to compare outcomes of patients who participate in cycling as means to resolve small bowel obstruction, non-operative and post operative ileus. Also to compare rates of blood clots, pneumonia, and hospital length of stay in patients who participate in cycling program compared to those that do not. You are invited to be in this study because you have been admitted with a small bowel obstruction, have slowed bowel function (also known as an ileus) or have had surgery on your intestines. Your participation in this research study will last only the duration of this current hospitalization. The total timeframe of this study will be 6 months.

Participation in this study will involve access to your electronic medical record by the principal investigator as well as an opt in option for the use of a recumbent bicycle or floor based bicycle for use as an alternate mobility option to assist with return of bowel function. All research studies involve some risks. A risk to this study that you should be aware of is the use of the bicycle equipment to ensure it is used safely and properly. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. This is not a treatment study. Your alternative is not to participate. There may be other choices available to you. Some other choices may include simply continuing with routine walking to facility mobility. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

2. INTRODUCTION

You are invited to be in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to be in this study because you have been diagnosed with small bowel obstruction, have slowed bowel function (also known as an ileus) or have had surgery on your intestines. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the researchers to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

This study will take place at Atrium Health Cabarrus.

3. WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to offer another option for mobilizing to help your bowels to begin functioning after surgery or if you have a small bowel obstruction. Recumbent or stationary bicycles are

already used in the outpatient setting, especially by physical therapists. There are previous studies that show that cycling helps stimulate the contraction of the muscles of the intestines. The principal investigator is looking to answer the following questions:

1. Does the use of cycling help your bowels begin working more quickly after surgery compared to walking around the nursing unit?
2. Does the use of cycling help resolve small bowel obstruction more effectively than walking around the nursing unit?
3. Does the use of cycling help decrease the rate of blood clots and development of pneumonia?
4. Does the use of cycling help decrease your stay in the hospital?

4. Who is Sponsoring this Study?

This is no sponsor to this study.

5. How Many People Will Take Part in the Study?

100 people will be included. Some people may be screened for the study but will not be eligible to participate.

6. How Long Will I Be in the Study?

Your physical participation in the study is planned to last only for the length of time you are in the hospital. The total study timeframe is 6 months.

7. What Is Involved in the Study?

You will be asked for your permission to have access to your electronic medical record for the following data:

- Whether or not you had surgery
- Type of surgery
- Whether or not you have a small bowel obstruction or ileus diagnosis
- Did you develop a post operative ileus
- Age range by decade
- Did you opt in for cycling vs. opt out.
- Did you experience a blood clot within 30 days after discharge
- Did you get pneumonia within 30 days after discharge
- What was your hospital length of stay

If you choose to opt in to the cycle option you will also be asked to access your electronic medical record for the following data:

- Length of time spent cycling
- Quantity of cycle sessions each day
- Distance cycled
- Heart rate variance before and after session
- Required cessation of therapy due to intolerance (deemed by nursing staff or Physical Therapy)
- Length of time to flatus (passing of gas)
- Length of time to first bowel movement

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- Venous thromboembolism (blood clot) occurrence within 30 days post discharge
- Pneumonia occurrence within 30 days post discharge
- Hospital length of stay

You may choose to opt in to cycle therapy as well as allow access to the aforementioned information in your electronic medical record as above. Or you may choose to continue with current practice of only ambulation by your surgical team but allow access to the aforementioned information in your electronic medical record as above. Physical therapy will be consulted for cycle therapy if you so choose. The physical therapy team will help to determine which therapy bike will be appropriate, either the recumbent bicycle or the floor bicycle. If the recumbent bicycle is appropriate, the recumbent bike will be stored on the postsurgical 1 unit. If the floor bicycle option is chosen for you, you will be assisted out of bed to use floor cycle bike in your patient room. You will already have the use of the "Massimo" monitor on your nursing unit, but physical therapy and nursing will monitor your heart rate and oxygen level throughout using the monitor. Unless you choose to utilize resistance, resistance setting on the bicycle will not be used. A full set of vital signs will be obtained before and after cycle therapy (blood pressure, heart rate, temperature, oxygen level). Length of cycle time can be determined by you, but not to exceed 20 minutes.

After you demonstrate comfort and safety in using either cycle modality, you may participate in this activity with nursing staff but will not require physical therapy presence at the time of use. This will allow the you to participate multiple times a day if you so choose. There will be no requirement for frequency upon which you participate in cycle therapy. You may participate as many days, and as many times a day, as you choose. The display screen will document time in activity, distance, and speed and this will be documented by nursing staff.

If you take part in this study, you will not have any additional tests or procedures. The only difference in activity in addition to standard of care is offering of cycling therapy with the recumbent bicycles or floor bicycles as above. You will not need any additional follow up. You may refuse cycle therapy at any time if you do not like the activity.

8. WILL I RECEIVE THE RESULTS OF THE STUDY?

Research results that are clinically relevant **can be disclosed to you** at the completion of the study if you so choose. However, the results of the study will not have any specific identifiers of any of your personal information.

If you so choose, we can send the outcomes of the studies to your personal email. Even if you do not wish to know the results of the study, you can still participate in this research study.

Do you want to receive an email with the results of the study be sent to your email address?

[ ] Yes [ ] No _____ Initials

_____ Email address

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EMAIL COMMUNICATION. By providing my email address, I give permission for Advocate Health, Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

9. WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk/inconvenience to you regarding use of a recumbent or floor bicycle. This includes possible injury from riding the bicycles. The risk of harm or discomfort that may happen because of taking part in this research study however is not expected to be more than in daily life or from routine physical or psychological examinations or tests. Additional risk includes possible loss of confidentiality. You should discuss the risk of being in this study with the study staff.

10. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the results of this study will benefit other people in the future as well. The benefits of participating in this study may be: improved option for mobility, private mobility in the cycle room or in your own patient room, quicker resolution of ileus or bowel obstruction, prevention of ileus post operatively, prevention of blood clots, prevention of pneumonia and potentially decrease length of stay.

11. WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study.

12. WHAT ARE THE COSTS?

Study costs, including any study products or procedures that would only be done as part of the study will be paid for by the principal investigator or grants. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

13. WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

14. Will Your Research Records be Confidential?

Your participation in this research and any study records created about your participation will be kept as confidential as possible. The overall results of this study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be shared and all data will be stored electronically in a HIPAA approved database.

15. WHAT IF I AM HARMED FROM BEING IN THE STUDY?

The probability and magnitude of harm or discomfort anticipated in this study are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test.

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16. WHO WILL SEE MY PROTECTED HEALTH INFORMATION?

Who may have access to my information:	*Purpose:*
Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor	To oversee the study and make sure the information is correct.
Consultants and employees of Advocate Health – Wake Forest University School of Medicine, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.
Monitors, auditors, IRB or other regulatory agencies may be granted direct access to your medical record.	To verify clinical trial procedures or data.

By signing this form, you are giving the researchers permission to use and share your personally identifiable health information. This includes direct access to your medical records. If you have questions about this, please ask the study doctor.

How will my information be used for this study?
You must authorize the use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study.
- to review the study, and to check the safety and results of the study.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care.

The collected information may contain your name, date of birth, dates relating to various medical procedures, and/or other identifying information.

How will my information be kept confidential?
We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form.

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Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually, the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves the organization we cannot control how it is used, and the law may not require other groups to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the principal investigator. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

[redacted]

If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

17. What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

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18. WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study contact the study investigator, Mallory Royall at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact [redacted].

19. Signatures

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have had ample time to consider participation in the study and have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I understand the research study and voluntarily agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
- I agree to follow the investigator's instructions.
- I understand and agree that representatives from the sponsor, regulatory authorities and the institutional review board will be granted direct access to my medical records.
- I understand that I may decide to refuse participation or stop participating at any time without penalty and without affecting the quality of my health care or the relationship with the study doctor.
- I understand that there may be consequences to my withdrawal from the study as noted within this document.
- I understand and agree that personal information about me will be collected in this study and from my medical records, and used and processed (manually and by computer) for the purposes of the study by the manufacturer of a medical device used in my treatment or any other designated party that is involved in the study (e.g. hospital, study doctor, regulatory authorities, ethics committees).
- If I so choose, I have provided the name of a person to be contacted by the principal investigator in case I cannot be reached for follow-up.

_____Initial if you agree to allow access to your electronic medical record only.

_____Initial if you agree to allow access to your electronic medical record and opt in to the cycle therapy option.

_____

Participant signature Date Time AM/PM

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Name of person obtaining informed consent (print)

Signature of person obtaining informed consent (print) Date Time AM/PM

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