Official Title: LCI-PED-NOS-EXER-001: Just Move. A Randomized Controlled Trial Investigating Exercise in Pediatric Oncology Patients
NCT# 05058508
IRB-Approved Date: 06/05/2026

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION
For
SUBJECTS WHO TURN 18 & PARENTAL/GUARDIAN PERMISSION

Sponsor / Study Title:	**Levine Cancer Institute / Just Move. A Randomized, Controlled Trial Investigating Exercise in Pediatric Oncology Patients**
Protocol Number:	**LCI-PED-NOS-EXER-001**
Principal Investigator: (Study Investigator)	**Jennifer Pope, MD**
Telephone:	[redacted]
Address:	**Atrium Health** **Levine Children's Hospital** [redacted]

Please read this form carefully. Take time to ask the Study Investigator or Study Staff as many questions about the study as you would like. The Study Investigator or Study Staff can explain words or information that you do not understand. Reading this form and talking to the Study Investigator or Study Staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. Participation in this study is completely voluntary.

If you are the parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When "you" appears in this form, it may refer to you or your child.

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted]

INTRODUCTION

The Study Investigator listed on the first page of this form is asking you to participate in this research study at Levine Children's Hospital (LCH), Levine Children's Cancer and Blood Disorders Clinic, and Atrium Health (AH). The purpose of this study is to see if there are physical and emotional benefits to participating in a structured exercise regimen (a planned

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course of exercise) for those who are ages 2-25, are newly diagnosed with a blood or solid tumor cancer, and are currently undergoing or will begin cancer treatment. You are being asked to take part because you have recently been diagnosed with a blood or solid tumor cancer, are 2-25 years old, and are undergoing or scheduled to begin cancer treatment.

Young children going through treatment for cancer are at risk of inactivity and the treatment of childhood cancer has been linked to decreased heart function, decreased muscle strength, increased fatigue, and altered physical functioning. This study is being done to see if an exercise regimen in the age group of 2-25 years old will increase, or at least maintain, their physical functioning and quality of life while undergoing cancer treatment. This study will also see if the exercise regimen will decrease common adverse effects of chemotherapy, specifically blood clots, skin ulcers, constipation, nausea and vomiting. The study team will collect information on adverse events that occur with those who are on the intervention (exercise) arm, if the events are felt to be directly related to the exercise. An adverse event is an undesirable experience associated with a medical product or intervention; in this study, this will be the exercise regimen.

This is a randomized, controlled study, which means you will be randomized (assigned by chance) to one of two "arms" or groups of subjects. One group of subjects will be assigned to the Intervention (exercise) arm and will be given an exercise regimen which will be done for a minimum of 30 minutes at least five days per week. The other group of subjects will be assigned to the Standard of Care (control) arm and will simply be encouraged to remain active during their cancer treatment without a structured exercise regimen to follow. The randomization will be 1:1, meaning for every subject who gets assigned to the intervention arm, one will also be assigned to the control arm. There is a 50% chance of getting assigned (randomized) to either the intervention or control arm. The assignment to either study arm is chosen randomly by a computer system.

Your cancer treatment will continue as planned whether or not you participate in this study.

Approximately 60 subjects will be enrolled into this study.

You (or your child) will be asked to participate in the study until the end of their cancer treatment, or for eighteen months, whichever comes first. Study participants who have ALL (Acute Lymphoblastic Leukemia) will remain on the study until their second cycle of maintenance chemotherapy is complete.

WHAT WILL HAPPEN DURING THE STUDY?

To participate in this study, you will need to review, sign and date this consent form and provide authorization for the release of your medical records for research purposes. By doing so, you are giving us permission to determine if you are eligible to participate in this study. The following is what happens at each study visit:

Baseline:

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- You will be asked questions about your demographics (age, race, presence of caregiver)
- You will also be asked questions about your medical history (cancer diagnosis, history of bleeding or clotting disorders, constipation, nausea, vomiting, history of skin ulcers and any current skin breakdown)
- Start date of cancer treatment will be collected
- 6-Minute Walk test (see below for more information)
- BOT-2 Brief (for subjects 4 and older) or PDMS-2 (for subjects ages 2-3) (see below for more information on both of these)
- Peds QL Cancer Module (see below for more information)

Monthly:

- Start date of cancer treatment collected (if this had not started at Baseline)
- 6-Minute Walk test
- Peds QL Cancer Module
- Patient Activity Tracker Form for subjects enrolled on the intervention arm (completed at home and returned to the research staff)

Quarterly (to be completed every 3 months):

- BOT-2 Brief or PDMS-2 (depending on age)

End of Study visit:
This visit will be completed within 4 weeks of completion of cancer treatment or end date of second cycle of maintenance cancer treatment for study participants with ALL (acute lymphoblastic leukemia).

- End date of cancer treatment collected (or end of second cycle of maintenance treatment for subjects with ALL)
- 6-Minute Walk Test
- BOT-2 Brief or PDMS-2 (depending on age)
- Peds QL Cancer Module
- Patient Activity Tracker Form for subjects enrolled on intervention arm (completed at home and returned to the research staff)

ADDITIONAL/MORE DETAILED INFORMATION

Study Assessments
A description of the study assessments used in this study are as follows:

6-Minute Walk Test*:* This assessment will be used with all subjects in this study. This is a timed walk that assesses endurance. Subjects will be timed to assess how far they can walk in 6 minutes.

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Bruininks-Oseretsky Test of Motor Proficiency (BOT-2)*:* This assessment is used for subjects ages 4 and older. This tool scores the subject's fine motor precision, fine motor integration, manual dexterity, bilateral coordination, balance, speed and agility, upper limb coordination, and strength. Results are then compared to previously established norms based on age and gender.

Peabody Developmental Motor Scale (PDMS-2)*:* This assessment will be used with subjects in this study ages 2-3. For subjects who enroll to the study at 2 to 3 years of age and initiate PDMS-2 testing, they will transition to BOT-2 testing once they turn 4 years of age. This tool scores subjects on gross and fine movement skills. It assesses reflexes, stationary performance, locomotion, object manipulation, grasping, and visual-motor integration. Results are then compared to previously established norms based on age and gender.

Pediatric Quality of Life Inventory (PedsQL Cancer Module): This assessment will be used with all subjects in this study. This tool measures health-related quality of life in children and adolescents with acute and chronic health conditions. It assesses physical, emotional, and social functioning through self-reported and parent reported surveys. Subjects aged 8 years and older will complete the PedsQL for themselves. A parent/guardian will complete the Parent Report PedsQL for subjects younger than 8 years old. If a younger child turns 8 at any time after the first survey is completed by parent/guardian, the parent/guardian should continue to complete the Parent Report PedsQL. Subjects ages 13-17 will complete the "Teen" PedsQL and subjects 18 or older will complete the "Young Adult" PedsQL. Otherwise, the subject (or parent/guardian) will complete the appropriate age-related PedsQL.

Pediatric Activity Tracker: This form will be used with all subjects randomized to the intervention arm. Information includes activity performed, duration of time, and if the subject was inpatient or outpatient on the day of activity. The Patient Activity Tracker assessments will be filled out daily by subjects, parents or caregivers and reviewed monthly during the study and at the end-of-study visit.

Adverse Events

There are specific adverse events which your Study Investigator may collect information about during this study. This information will be collected beginning at your Baseline visit through the End of Study visit. Let your study team know if you experience any of these potential adverse effects from cancer treatment, which include:

- Blood clot formation anywhere in your body
- Ulcers on your skin
- Severe nausea
- Severe vomiting
- Constipation

For subjects on the Intervention arm (exercise program): Information about adverse events that your Study Investigator feels are related to the prescribed exercise will be collected, beginning from the Baseline visit through the End of Study visit. Let your study team know if you experience any of these potential adverse events, which include:

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- Bone fracture
- Fall
- Muscle aches/pain

YOUR ROLE IN THE STUDY

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include telling the truth about your medical history and telling the Study Investigator (or your medical doctor) if you have any new medical problems while you are on the study. You and/or your parent/guardian will also need to complete and return the Patient Activity Tracker as instructed.

RISKS OF THE STUDY

For ALL subjects:
Emotional distress: Some questions in the questionnaires could create emotional distress or confusion. Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

For subjects on the intervention arm:
Some of the exercises may cause physical distress. In event of physical distress, exercises will be discontinued, and subject will be re-evaluated by the medical team and physical therapy to assess for needs in modification of exercises. If cardiac dysfunction (that, in the opinion of the investigator, would be unsafe for the child to participate in the exercise program) develops during treatment, the exercise regimen will be evaluated for safety and feasibility to continue. If cardiac symptoms occur during study, exercises will be discontinued, and subject will be evaluated by medical team and possible consultation with cardiology if necessary.

Unknown Risks

You might have discomforts that are not listed in this form. Tell the Study Investigator or Study Staff right away if you have any problems.

EXCLUSION CRITERIA

- Known cardiac dysfunction that in the opinion of the investigator, would make it unsafe for you to participate in the exercise program
- Recent or planned surgery that will limit your ability to participate in the exercise program
- Primary CNS tumor
- Osteosarcoma

ALTERNATIVES TO BEING IN THE STUDY

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You do not need to take part in this research study. If you do not participate, you could stay physically active during treatment without a structured exercise program, follow any other recommendations by your physician, or you could do nothing at all.

POTENTIAL BENEFITS OF BEING IN THE STUDY

You may or may not receive any benefit from being in the study. It is possible that you may have improved or maintained physical functioning or quality of life, stay the same, or get worse. You may or may not have a decrease in adverse events such as clot formation, skin ulceration, or significant nausea and vomiting. If you take part in this study, other people ages 2-25 undergoing treatment for cancer may be helped.

COSTS OF BEING IN THE STUDY

The study surveys and procedures required by the study are provided at no cost to you. The funder, the Atrium Health Foundation, pays for them. Visits to your medical clinic for your usual care and cancer treatment will remain your responsibility.

YOUR PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study.

STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

The Study Investigator asking you to participate in this study has not received, nor will receive money or other benefits for personal use from the study sponsor. However, the funder will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the Study Investigator or Study Staff is associated.

COMPENSATION FOR INJURY

In the event that you are injured as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You will be responsible for deductibles, co-payments, and co-insurance. There are no plans to pay or give you other compensation for the injury. You do not waive any legal rights by signing this consent form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

CONFIDENTIALITY

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The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by the Sponsor, by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

BEING A STUDY VOLUNTEER AND WITHDRAWING FROM THE STUDY

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

Information already contributed to the study will remain in the study even if you choose to withdraw. If you decide to no longer participate in the study for any reason, data which may have already been collected and processed will remain de-identified and part of the study.
If you decide to withdraw this consent (decide to stop participating in this study) at any point, no further questionnaires or data will be collected from you.

Your Study Investigator, medical doctor, or Levine Cancer Institute can remove you from this study for any reason at any time without your consent. Reasons include but are not limited to:

- You are non-compliant with study participation, in the opinion of the investigator
- You or your parent/legal guardian withdraw consent
- You are lost to follow-up
- Your provider believes study participation is no longer in your best interest
- You develop heart problems that, in the opinion of the investigator, would be unsafe for you to participate in the exercise program
- You complete the End of Study visit as planned
- The study is stopped by Levine Cancer Institute

Your Study Investigator will explain the reasons for your removal and will help arrange for your continued care, if needed. Once you are off the study, you will not participate in any further research procedures related to this study, including data collection.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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QUESTIONS

For questions about the study or in the event of a research-related injury, contact the study investigator using the contact information listed on the first page of this consent form.

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 the IRB at [redacted] or the Research Subject Advocate at [redacted]

You will be given a copy of this signed consent form.

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

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 Atrium Health, Wake Forest University School of Medicine, and 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 Atrium 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.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself, reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

How will my information be used for this study?

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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.
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial.
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care.
- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, 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. 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.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after

everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

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 study doctor. 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.

Jennifer Pope, MD
Torrey Hemby Center for Cancer and Blood Disorders
[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?

The authorization to use and share your information has no end date.

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

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject (if subject is age 18 or older) Date Time

_____
Printed Name of Research Subject

_____ ____/____/____ _____
Signature of Parent/Legal Guardian (if subject is under age 18) Date Time

_____
Printed Name of Parent/Legal Guardian (if subject is under age 18)

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STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject/parent/legal guardian the nature and purpose of the above study. There has been an opportunity for the subject/parent/legal guardian to ask questions about this research study. I have been available to answer any questions that the subject/parent/legal guardian has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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