Principal Investigator: Dr. Michael Goldfarb, MD
Division of Cardiology, Jewish General Hospital, McGill University

Consent to Participate in a Clinical Research Study:

Early Mobilization of Older Adults in the Cardiovascular Intensive Care Unit

Invitation to participate in a research study

You are invited to participate in a research study about early movement and activity in older adults who are in the Cardiovascular Intensive Care Unit at the Jewish General Hospital.

Purpose of the study

Older adults are more likely to have physical limitations prior to coming to the hospital and are at higher risk for muscle loss and decreased strength while in hospital. As a result, older adults are more likely to have difficulty performing activities of daily living and loss of independence after leaving the hospital, which can lead to a worsened quality of life.

The aim of our study is to evaluate if an early physical movement program in the hospitalized people is safe and effective at improving physical abilities during the hospital stay and after leaving the hospital.

Description of participant involvement

If you are a patient in the hospital who agrees to participate, a researcher will review your medical chart after you leave the hospital. A member of the research team may ask you questions about your physical abilities prior to coming to hospital. You may be asked to wear an accelerometer around your thigh to measure your movement during hospitalization. You may be asked to be measured by a scale that measures the amount of muscle on your body.

One and twelve months after you leave the hospital, a member of the research team will call you and ask questions about your physical abilities and your health-related quality of life. These phone calls should take less than 10 minutes.

Risks and Discomforts

There are minimal risks with participating in this study. The accelerometer may cause discomfort or irritation at the site where it is attached and it can be removed at any time. There are no risks to being measured by the scale.

Benefits

We cannot guarantee that you will receive any benefits from this study. However, information learned from this research may lead to a better treatment in the future for older people who are hospitalized with heart disease.

Alternatives

If you do not wish to participate in this study, you are entitled to receive the same care from your usual doctor without any penalties or restrictions. You will be able to participate in the early mobilization program even if you do not participate in this study. All patients in the Cardiovascular Intensive Care Unit are eligible for the early mobilization program even if they do not participate in this study.

Compensation

There is no compensation offered for your participation in this study.

Should you suffer any harm

Should you suffer harm of any kind following any procedure related to the research study, you will receive the appropriate care and services as required by your state of health.

By agreeing to participate in this research study, you do not give up any of your legal rights nor discharging the doctor in charge of this research study, the sponsor of the institution, of their civil and professional responsibilities.

Voluntary participation/withdrawal

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the doctor in charge of this research study or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the doctor in charge of this research study or the clinical team.

The doctor in charge of this research study or the WCMH MBM Research Ethics Committee may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

However, before you withdraw from the study we suggest that you contact the research coordinator or the principal investigator for safety reasons.

If you withdraw or are withdrawn from the study, the information collected during the study will nonetheless be stored, analyzed or used to protect the scientific integrity of the research project.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible. We may also learn information about you that was not known before, if this happens we will notify you and ensure that you receive appropriate medical care.

You will be given a copy of this consent form when you give your consent to participate in this study and you may request additional copies thereafter.

Funding

The study is funded by the division of cardiology of the Jewish General Hospital.

Confidentiality

All of the information (including your name and any other identifying information) will be coded and kept strictly confidential and will not be revealed to other parties except the investigators and delegates. The Research Ethics Committee and legal authorities such as Health Canada will have access to the collected data without compromising your confidentiality.

All information obtained will be anonymized, coded, and saved on encrypted workstations. You will not be identified in any publication of this study. All study documents will be kept in secured files by the investigators until the study is concluded. If you withdraw from this study, all information collected up to the point of withdrawal may still be used in order to preserve the scientific integrity of the study.

Contact Numbers

For questions concerning this research project, you may contact Dr. Michael Goldfarb at (514) 340-8222 ext. 25801.

For questions concerning your rights as a participant in this study, you may contact the Hospital Ombudsman, Mrs. Rosemary Steinberg, at (514) 340-8222 extension 25833.

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STATEMENT OF CONSENT

I have reviewed the information and consent form. Both the research study and the information and consent form were explained to me. My questions were answered, and I was given sufficient time to make a decision. After reflection, I consent to participate in this research study in accordance with the conditions stated above.
I authorize the research study team to have access to my medical record for the purposes of this study.
I do not give up any of my legal rights by signing this consent form.

I agree to take part in this study.

_____	_____	_____
Printed name of participant	Signature of participant	Date

Signature of person obtaining consent
I have explained the research project and the terms of this information and consent form to the research participant, and I answered all his/her questions.

_____	_____	_____
Name of person obtaining consent	Signature	Date

Signature of Principal Investigator
I certify that this information and consent form were explained to the research participant, and that the questions the participant had were answered.
I undertake, together with the research team, to respect what was agreed upon in the information and consent form, and to give a signed and dated copy of this form to the research participant.

_____	_____	_____
Name of the principal investigator	Signature	Date