Implementation of Frailty Care Bundle (FCB) for older people in acute care settings: an implementation science study

Patient participant information leaflet

Principal Investigator Name: Professor Corina Naughton
Principal Investigator Role: Professor of Nursing in Older Person Health Care, University College Cork, Telephone number 021 490 1551

About the project:

This is a research study funded by the Irish Health Research Board (HRB) and is being led by University College Cork.

We are undertaking a study to look at nutrition and mobilisation (e.g. walking) in patients during hospital admission. There are several factors which can influence how much people eat, drink or walk while in hospitals. Some of these factors are due to the person's illness, but there are also hospital practices that can impact these aspects of nursing care. This project is helping nursing staff to critically look at how patient nutrition, mobilisation and patients and families are involved in decisions about these activities. Over the next eight months, nurses will introduce new ways to deliver care with a focus on optimising nutrition, mobilisation and patient involvement in decisions.

During the study period, you may notice research staff observing mealtimes and what kind of activities patients are engaged in, e.g. sitting in a chair, walking, lying in bed. We are not collecting any information that can identify any patients. We are using this information to feedback to ward staff on how care can be improved. We also would like to collect detailed information on some patients during their hospital stay.

What does the study involve?

We are collecting information from patients in four ways

1) We would like your permission to collect information from your medical records about your health and we would like to ask you some questions about your normal level of activity prior to hospital and your opinions on hospital nutrition and walking while in hospital. A member of the research team will ask you questions and record your answers on an electronic device (Ipad). The interview will take about 15 minutes.
2) We would like to measure your walking time over 3 meters and your hand grip strength
3) We would like to measure how many steps you walk while you are in hospitals. To do this, we will use an accelerometer that is worn on the ankle using a velcro strap. The accelerometer is worn for up to 7 days or until you are discharged if this is sooner.

4) Finally, we would like to contact you by phone one month after you are discharged from the hospital. We will ask you about your health and your level of activity, including walking. We will also ask your opinion of the nutrition and

level of activity you were able to undertake while in hospital. The interview will take 10-15 minutes and can be scheduled at a time that suits you.

Why are we contacting you?
We are inviting as many patients as possible to participate in the data collection during their hospital stay so that we can hear the views and experience of patients with a broad range of medical conditions.

Do I have to take part?
No, you do not have to participate in the study. If you decide not to participate, it will have no impact on any aspect of your care, including nutrition or mobilisation. You are also free to change your mind and withdraw from the study at any time.

What will my involvement require?
If you agree to take part, we will ask you to sign a consent form so we can use your data as part of the study. We will complete the questionnaire and other measures. The researcher will attach the accelerometer to your ankle. A member of the research team with visit you daily to ensure you are happy to continue in the study.

What are the possible disadvantages or risks of taking part?
There is minimal risk above standard clinical care in participating in this project. If the accelerometer begins to be bothersome, you can ask a nurse on the ward to help you remove it. If you become tired at any stage during the interview you can ask the researcher to stop and reschedule the meeting.

What are the possible benefits of taking part?
There may be no direct benefit to you in taking part in this study. The study is part of our continuous effort to provide the best care we can to patients. The study aims to help identify ways nutrition, mobilisation and patient involvement in decision making can be optimised as part of normal ward culture.

Data Protection Notice

At University College Cork, we treat your privacy seriously. Any personal data which you provide to the University will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation. This notice sets out details of the information that we collect, how we process it and who we share it with. It also explains your rights under data protection law in relation to our processing of your data.

Who we are

Throughout this Notice, “we”, “us” and “our” refers to University College Cork, as study sponsor. For more information about us, please refer to our website: *www.ucc.ie*

How we will use your personal data

By participating in the study and performing the study exams, information from you (also called “personal data”) will be collected for the study purposes mentioned in the Patient information leaflet above. This personal data includes, for example:

- information that directly identifies you (such as your name, telephone number);
- your gender,
- information on your health and medical condition including your medical history;
- Information collected using accelerometer on the distance you walk in hospital.

Personal data collected at any time during the study will be kept strictly confidential. To ensure confidentiality, the data generated during the study is **coded** with a number that will identify you in the study. Any information that leaves the clinical site will be labelled with your code instead of your name. Every person that has access to your uncoded data is subject to professional secrecy and confidentiality.
Data that directly identifies you (uncoded data) is stored in a research files stored at the clinical site in which the data have been obtained. A list or 'key' linking your study number to your name will also be kept securely (locked cupboard in a room with restricted access) by the investigator.
During the course of the study, if you disclose information that we feel has implication for your safety or the safety of other people, we will have to relay this information to a member of your nursing or medical team. Before we do this, we will discuss the issue with you.

Who will access my personal data?

Your uncoded data will only be accessible to the study investigator and study staff. Results of the study will be provided to the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) in compliance with national and international regulations on clinical studies.

The purpose and legal basis for collecting your data

Any personal data you provide to us during the course of this study will be processed fairly and lawfully.

Signing the Informed Consent Form means that your personal data will be used for the purposes outlined in the Patient information leaflet (PIL).
Personal data collected during this study and the results of the study may be presented for scientific purposes. However, you will never be identified individually during these presentations. Your identity will not be revealed in any reports or publications.
The clinical site and the investigator will use your personal data within the scope defined above.
The General Data Protection Regulation allows us to process your data because you have provided your consent. You are entitled to withdraw your consent at any time.

How long we will keep your data

The personal data collected in the study will be kept for a period of at least 5 years after the end of the study. Thereafter, they may be stored for a further period of time for legal reasons (e.g. revised retention obligations), or more if required by law.

Your rights

You have various rights under data protection law, subject to certain exemptions, in connection with our processing of your personal data, including the right:

- to find out if we use your personal data, access your personal data and receive copies of your personal data;
- to have inaccurate/incomplete information corrected and updated;
- in certain circumstances, to have your details deleted from systems that we use to process your personal data or have the use of your personal data restricted in certain ways;
- to object to certain processing of your data by UCC;

- to exercise your right to data portability where applicable (i.e. obtain a copy of your personal data in a commonly used electronic form;

- to withdraw your consent to the processing of your data at any time without giving a reason by notifying your decision to the investigator. This will not affect the lawfulness of processing data about you based on your consent before the withdrawal. If you withdraw your consent for data processing, your participation in the study stops and no further data will be collected from you. Your study physician will present you the options you have concerning your personal data.

- Along with study withdrawal, you have the right to request the deletion of data about you if your data are no longer necessary for the purposes of processing or there is no other legal ground for their further processing.

If you wish to exercise any of these rights, please address your request to the study physician or the Information Compliance Manager, University College Cork (details below).

Questions or Complaints

If you have any queries in relation to this study please contact Professor Corina Naughton (details below). If you have any complaints in connection with our processing of your personal data, you can contact UCC's Information Compliance Manager: **Information Compliance Manager, Office of Corporate & Legal Affairs, University College Cork, Western Road, Cork E: foi@ucc.ie Tel: +353 21 4903949**

You also have the right to lodge a complaint with the Data Protection Commission if you are unhappy with our processing of your personal data. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.

What if there is another concern?
Any complaint or concern about any aspect of the way you have been treated during the course of the study will be addressed; please contact Professor Josephine Hegarty, Head of School of Nursing and Midwifery, University College Cork (J.Hegarty@ucc.ie)
Full contact details of Principal Investigator:
Professor Corina Naughton,
Professor of Nursing in Older Person Health Care, University College Cork

Telephone number 021 490 1551 corina.naughton@ucc.ie

Who has reviewed the project?

This study was submitted to Cork Research Ethics Committee (CREC).

Thank you for taking the time to read this Information Sheet.