



CYCLE RCT Telephone Script

The following general statements may be used in the initial telephone conversation with substitute decision makers (if required). Please note that it is difficult to script the conversation given that it is not possible to anticipate the responses of the SDM with any degree of certainty. The research coordinator on the telephone will need to adapt the dialogue to the person on the phone.

Hello (insert name of SDM). My name is (insert name of research personnel) and I am the research coordinator in the ICU at (insert name of hospital here). As a teaching and research hospital, we participate in studies that to improve our understanding of disease and improve the detection, prevention, and treatment of critical illness. It is important to offer opportunities for research participation to our patients and families for their consideration. When patients like (insert name of patient) are in the ICU, we can't usually talk to them due to the severity of their illness and the technology and drugs they need. We ask family members to act as substitute decision makers and to make decisions for the patient, based on their best knowledge of what the patient would want for themselves if they could speak. Participation in any type of study is entirely voluntary and of course you don't need to agree. If you agree, you have the right to withdraw from the study at any time.

As the doctors have explained to you, (insert patient name) has been admitted to the ICU and requires a machine to help with breathing. When patients need the breathing machine, they get very weak, all over, but particularly their leg muscles. One way of helping patients stay strong is to offer in-bed exercise with use of a special in-bed bicycle, which one previous study found helps patients walk further when they leave the hospital. At (insert hospital name), we are working on a study funded by the Canadian government to better understand if it is helpful and safe to offer in-bed cycling to patients who are on breathing machines early in their ICU stay compared to routine physiotherapy. This involves the bike that is brought right to the patient's bedside. Would you be willing to discuss the possibility of (insert name of patient) participating in a cycling research study with me?

If the SDM is willing to discuss the possibility of research participation, we would then review the study in more detail and review the contents of the consent form. We would also send a copy of the consent form via a designated faxline if available to assist the SDM in the decision making process. We would endeavor to have the SDM sign the original consent form at their earliest convenience when they come into ICU (i.e., their next visit to the hospital).

The purpose of our study is to understand if it is possible to offer in-bed cycling to patients like (insert patient name). In this study, patients will receive either 30 minutes of cycling, 5 days per week, and regular physiotherapy as long as they are in the ICU or regular physiotherapy. Patients will be randomly assigned, like the flip of a coin, to cycling or regular physiotherapy. Patients will receive these sessions from specially trained physiotherapists who will closely monitor (insert patient name) during all sessions. In this study, we will measure patients' strength and function, like walking, while they are in the ICU and before they leave the hospital.

As per our usual ICU research practice, we document our consent discussion both in our study file and in the patient's medical chart. As usual, we will ensure the presence of a witness to the conversation to attest to the content of the discussion if occurring via telephone.