Consent to Participate in a Research Study

The Impact of IADL Interventions on Discharge Readiness for Clients with a Musculoskeletal Condition Admitted to Inpatient Rehabilitation

Institutional Review Board
Protocol Number
6031
Approval Valid
7/30/24-12/31/24

Key Information

You are being invited to participate in a research study. This document includes important information you should know about the study. Before providing your consent to participate, please read this entire document and ask any questions you have.

Do I have to participate?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide to participate, you will be one of about 40 people in the study.

What is the purpose of the study?

The purpose of the study is to determine the impact that instrumental activities of daily living (IADL) intervention and training has on individuals' perceived discharge readiness and independence with self-care tasks for those admitted to an inpatient rehabilitation facility with a musculoskeletal condition. Examples of IADLs are cooking, cleaning, shopping, and other high-level tasks that you may need to complete at home after you discharge from the facility. This research may improve the quality of care for clients admitted to the inpatient rehabilitation setting with a musculoskeletal condition by promoting inclusion of broader areas of interventions into occupational therapy as a standard of care.

Where is the study going to take place and how long will it last?

The research procedures will be conducted at Pikeville Medical Center. This study will take place during your inpatient rehabilitation stay and will take 90 to 120 minutes per day 3-7 days per week. This time will take place during your already planned occupational therapy sessions during the course of your inpatient rehabilitation stay.

What will I be asked to do?

The researcher will be using your evaluation and discharge scores using the documentation system at this setting. You will then be asked to complete the Readiness for Hospital Discharge Scale with an additional question added by researcher for a total of 10 questions which you will answer at the start of your care/stay and at the end of your care/stay. You will be placed in either the control group or the experimental group. The control group participants will receive the normal standard of care which includes basic self-care known as activities of daily living training and therapeutic activities/therapeutic exercise (range of motion arc, arm bike, therapeutic exercise using weights and rickshaw machine, fine and gross motor tasks, etc.). Basic self-care training will include interventions addressing bathing, dressing, toileting, toileting transfers, grooming and

feeding. Goals established by the evaluating occupational therapist at start of care will be to increase levels of independence with basic ADLs to aid in return home to assess level of discharge/home readiness as described by the patient. The experimental group participants include the standard of care of basic self-care training as well as therapeutic activities/therapeutic exercise, with the addition of higher-level occupation-based activities known as instrumental activities of daily living training including but not limited to interventions of: household management tasks, shopping, laundry, medication management, and meal preparation. Goals established by the evaluating occupational therapist at start of care will be to increase levels of independence with both self-care and IADLs to aid in return home to improve discharge/home readiness as described by the patient. The scoring which is standard practice at this facility as well as your responses on the Readiness for Hospital Discharge Scale will be used for comparison between the groups. This researcher is also your occupational therapist who will be implementing your care during your stay.

Are there reasons why I should not take part in this study?
No, only if you do not want to participate.

What are the possible risks and discomforts?
To the best of our knowledge, the things you will be doing have no more risk of harm or discomfort than you would experience in everyday life.

What are the benefits of taking part in this study?
You are not likely to get any personal benefit from taking part in this study. However, you may have a better idea of your perceived readiness for discharge based on your responses on the Hospital Readiness for Discharge Scale. Your participation is expected to provide benefits to others as it may improve the quality of care for clients admitted to the inpatient rehabilitation setting with a musculoskeletal condition by promoting inclusion of broader areas of occupation into occupational therapy intervention as a standard of care.

If I don't take part in this study, are there other choices?
If you do not want to be in the study, there are no other choices except to not take part in the study.

Now that you have some key information about the study, please continue reading if you are interested in participating. Other important details about the study are provided below.

Other Important Details

Who is doing the study?
The person in charge of this study is Kasi Gannon, OTR/L at Eastern Kentucky University. She is being guided in this research by Renee Causey-Upton, PhD, OTD, OTR/L, CLA, FAOTA. There may be other people on the research team assisting at different times during the study.

What will it cost me to participate?
There are no costs associated with taking part in this study.

Will I receive any payment or rewards for taking part in the study?
You will not receive any payment or reward for taking part in this study.

Who will see the information I give?
Your information will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about this combined information. You will not be identified in these written materials.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

However, there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court (if applicable: or to tell authorities if we believe you have

abused a child or are a danger to yourself or someone else). Also, we may be required to show information that identifies you for audit purposes.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained via the Internet. Third-party applications used in this study may have terms of service and privacy policies outside of the control of the Eastern Kentucky University.

Can my taking part in the study end early?

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to participate. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to end your participation in the study. They may do this if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the University or agency funding the study decides to stop the study early for a variety of reasons.

What happens if I get hurt or sick during the study?

If you believe you are hurt or get sick because of something that is done during the study, you should call Kasi Gannon, OTR/L at (606) 422-3200 or (606) 422-9550 immediately. It is important for you to understand that Eastern Kentucky University will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, Eastern Kentucky University will not pay for any wages you may lose if you are harmed by this study. These costs will be your responsibility.

Usually, medical costs that result from research-related harm cannot be included as regular medical costs. Therefore, the costs related to your care and treatment because of something that is done during the study will be your responsibility. You should ask your insurer if you have any questions about your insurer's willingness to pay under these circumstances.

What else do I need to know?

You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study.

We will give you a copy of this consent form to take with you.

Consent

Before you decide whether to accept this invitation to take part in the study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact the investigator, Kasi Gannon, OTR/L at (606) 422-3200 or (606) 422-9550. If you have any questions about your rights as a research volunteer, you can contact the staff in the Division of Sponsored Programs at Eastern Kentucky University at 859-622-3636.

If you would like to participate, please read the statement below, sign, and print your name.

I am at least 18 years of age, have thoroughly read this document, understand its contents, have been given an opportunity to have my questions answered, and voluntarily agree to participate in this research study.

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Signature of person agreeing to take part in the study Date

_____

Printed name of person taking part in the study

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Name of person providing information to subject