PATIENT INFORMATION SHEET

Southampton Mobility Volunteers: The use of trained volunteers to increase physical activity of hospitalised older people (SoMoVe)

We would like to invite you to take part in a research study. Before you decide whether or not you would like to take part in this study, we would like you to read this information sheet. This is important for you to understand why the research is being done and what it might involve.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more information about the conduct of the study.

Please take your time to read and decide whether you wish to take part.

Part 1

What is the purpose of the study?

The purpose of this study is to find out if the use of trained volunteers to help promote increased physical activity among older patients in hospital is possible and acceptable. Previous research has shown that physical activity levels of hospitalised older people is generally very low and this can lead to many negative effects including worsening independence in activities of daily living and poorer health outcomes . A few studies have been carried out to encourage early mobility and improve physical activity levels of older people in hospital and have shown positive results in reducing length of hospital stay, and improved physical function and reduced nursing home admissions.

In this study, volunteers will be trained by the therapy team to ensure that they are safe and well-equipped with the skills to promote increased physical activity. Patients who are able to walk on their own will be encouraged to walk with volunteers and patients who need extra help with walking will be encourage to do bed or chair-based exercises. This study will be carried out on 2 wards in the Medicine for Older People (MOP) department, ward G8 and G9.

Why have I been chosen?

You have been asked to take part in this study because you are an inpatient on ward G8 or G9 in the Medicine for Older People (MOP) department at University Hospital Southampton and you meet the eligibility criteria. Patients who are eligible for this study include any patients older than age 70, who have no medical or physical condition that may prevent their involvement in the study, and are able to give consent.

Do I have to take part?

It is up to you to decide whether or not you would like to participate. If you do agree to take part in the study you will be asked to sign a consent form to demonstrate your agreement. You are free to leave the study at any time without giving a reason. A copy of this information sheet and a signed consent form will be given to you to keep. If you choose not to take part in the study, or to withdraw from the study at any time, the standard of care you receive will not be affected at all and you will continue to receive excellent care during your stay in the hospital.

What will happen to me if I take part?

You will continue to receive usual care on the wards during your participation in this study. Additionally, you will also be encouraged by trained volunteers to either walk or take part in chair-based exercise, depending on your ability, twice a day during the weekdays. Each session will take on average about 15 minutes. However this is not a set time and you will be encouraged to mobilise as you feel able. This will continue for the duration of your stay in hospital until you are discharged from hospital. The consultant responsible for your care during your hospital stay will be informed about your participation in this study.

What will I have to do?

If you agree to take part in this study, we would like you to inform a member of the nursing staff. The researcher will then meet with you to answer any questions and obtain your written consent and proceed with the study. We will use a questionnaire to collect some information about you for the purposes of this study. We will be collecting information such as your age, general health, physical abilities and mental health. You will be given 2 wireless monitoring devices (StepWatch Activity Monitor and GENEActiv) which will measure your physical activity level during for the duration of your hospital stay. The devices

are light and waterproof and do not need to be removed during washes. They will be given to you once you have agreed to participate in the study and should be worn until the day you leave hospital. Your physical activities will be continuously recorded but the devices will not provide you with any feedback. You should keep the devices on at all times to make sure that the recording is accurate. The research team will monitor your devices daily to make sure that it is comfortable for you. The information that we gather from the devices will include the number of steps you take daily and the length of time and intensity of activities that you perform daily.

We will also invite a few patients to be interviewed to find out about their views and thoughts about this study. The interview will take place either by the bedside or in a private meeting room, depending on their preference. The interview will be conducted by a member of the research team and will be audio recorded.

What are the possible disadvantages and risks of taking part?

Previous studies have shown that increasing mobility and exercise does not increase the risk of falls. Nonetheless, it is still a potential hazard which will be addressed. Volunteers are trained to encourage patients to walk safely and at a comfortable pace. The walking session is mainly dependent on the patient and you can choose not to take part or limit yourself to a shorter session if you feel unwell or tired. Volunteers will check with the nurse in charge prior to any session to confirm that patients are safe to mobilise or carry out exercises. In the event of an injury or a fall, volunteers are trained to seek help from nursing staff immediately. The risk of sustaining and injury during bed or chair based exercise is very low.

What are the possible benefits of taking part?

Maintaining adequate physical activity levels during your stay in hospital can promote recovery of physical function and independence in activities of daily living. It may also reduce your risk of hospital acquired infection and potentially shorten your stay in hospital. Working with volunteers can be a sociable activity, and may make your hospital stay a little more interesting. By taking part in this study, you will also contribute significantly to further research as the information gathered during this study will help guide future studies.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1 of the information sheet.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What if new information becomes available?

Sometimes we get new information about the intervention being studied. If this happens, a member of the research team will tell you and discuss whether you would like to continue in the study. If you decide not to continue in the study it will not affect any aspect of your care, and if you do decide to continue in the study you will need to sign an updated consent form. If for any reason the research study stops, we would inform you.

What will happen if I don't want to carry on with the study?

If you do not wish to carry on with this study, you can withdraw at any time without giving a reason. If you decide to withdraw we would like to retain the use of anonymised (non-identifiable patient information) routine data and any data already collected which would be important for the overall study results. Similarly, it would be important to be able to record patients' outcomes such as date of hospital discharge and discharge destination.

What if there is a problem?

If you have a concern about any aspect of this research study, you should ask to speak to the researchers involved who will do their best to deal with your concerns (see contact details at the end of the information sheet).

If you still remain unhappy and wish to complain formally you should contact Patient Support Services (Tel: 023 8120 6325).

Will my taking part in the study be kept confidential?

Confidentiality will be ensured for all participants, and all data collected will be used only for scientific research purposes. Data will be stored on a password protected computer in a locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. Interviews will be recorded with your permission using a digital audio-recorder and all recordings made will be removed from the audio-recorder and transferred to a secure memory stick as soon as possible. This memory stick will then be stored in a locked filing cabinet in a secure office. The recordings will then be typed into a document and no names or any other details that might identify the participant will be included. All information will be anonymised (non-identifiable patient information) and each recording and document will be password-protected. In the analysis of results, your data will be used anonymously (non-identifiable patient information) and non-attributable (cannot be specifically identified) to any individual. Our procedures for handling, processing, storing and destroying data relating to your participation in the study are compliant with the Data Protection Act 1998. In accordance with the hospital's regulations we are required to keep your data secure for 10 years. For the purposes of monitoring research there is a possibility that the hospital Research and Development department will audit the data that we have collected.

Your data may be used in future studies by our research team looking at the characteristics of older people in hospital. If this happens, your data will be used anonymously (non-identifiable patient information) so you cannot be identified. Any new research studies using your data will be authorised by the local research ethics committee.

What will happen to the results of the research study?

The results of the research will be published in medical scientific journals. Research staff may also present the results at conferences and local meetings, and on the hospital website where it would be available to members of the public. You will not be identified in any report produced.

Who is organising and funding the research?

The research study is funded by the Department of Health through the National Institute for Health Research (NIHR), Collaborations for Leadership in Applied

Health Research and Care (CLAHRC), Ageing and Dementia: Improving Routine Clinical Care theme.

Who has reviewed the study?

This study has been reviewed and received favourable opinion by South East Coast-Surrey Research Ethics Committee. It has also been reviewed by the research and development team at University Hospital Southampton NHS Trust.

This information sheet is for you to keep. If you are interested in participating in this study, please speak to your nurse who will contact the research team. Thank you very much for reading this information and your consideration in taking part in the study.

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