The HAPPI Study: Developing and testing an assessment and care plan to support older people who live with frailty at home.

Participant Information Sheet

We would like to invite you to take part in our research study

Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if anything is not clear, or if you would like more information. You can contact us on the number at the end of this sheet.

Why is this research important?

We know that as we get older some people face challenges of multiple health problems which can lead to loss of resilience, independence and may become more frail. From the age of 80, between a quarter and a half of people will show some of the signs of frailty so it is important that we understand the causes and how best to manage the condition for the future. Like many long-term conditions frailty cannot be cured and as we are living longer, we need to understand how to empower people to live well into older age.

Our research aims to explore how frail people can be best supported at home and how community nurses need to work to provide individualised support. We want to explore if we can measure outcomes for patients such as being able to live at home, improve wellbeing, prevent falls and reduce the need for hospital care.

Who is funding and organising the research?

This study is being funded by the National Institute of Health Research and carried out by Helen Lyndon who is a Community Nurse and Research Fellow based at Plymouth University. Older people have been involved in designing the study so far including advising on the elements of the care and support that are important. Older people and carers will be part of the study steering and management groups that will oversee the research.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the XXX Ethics Committee.

What's Involved?

This study aims to find out if it is possible to develop an assessment and care plan based on the individual needs of frail older people that can be used by nurses in partnership with patients and their carers. We will undertake a small study to test this new assessment and care plan to see if it is practical and achievable. In this part of the study, there will be a group of people who receive the new assessment and care plan and a group who will receive care as usual. In the final part of this study we will

talk to frail patients, carers and nurses to explore their experiences of participating in the research study.

What would taking part involve?

Your General Practice have agreed to take part in this study and this means that patients of the practice will be randomly allocated to one of two groups: either to receive the new assessment and care plan intervention or to receive usual primary care. Your general practice will be allocated at random (by chance - like tossing a coin). Then as a patient of that practice, you will continue to receive the same treatment throughout the study. Whether you are allocated to the intervention or the usual care group, the study involves regular assessments over about six months with up three study visits at your home. If your decide to take part, your GP will be informed and your GP will be asked to provide information about your care to the research team.

We are aiming for 60 people with moderate or severe frailty to take part in the study. Half of those recruited will take part in the HAPPI assessment and care planning process and the other half will receive their usual primary care.

The HAPPI assessment and care planning process will involve up to six visits from a community nurse to you at home to work in partnership with you to assess your needs and develop a care plan to help address them. Usual care means just that “care as usual” from your GP, nurse or any other member of primary or community health services such as visits to your GP, medication, vaccinations etc.

All participants in the study will receive three study visits from the research team, one to gain your consent to take part and ask you questions to get baseline outcome measures. The other two visits will be at three and six months to follow-up on the outcome measures. This will involve you answering some questionnaires relating your health and well-being. It is expected that these study visits will last up to an hour each time.

Do I have to take part?

No. Participation is entirely voluntary. It is up to you to decide whether or not to take part in the study. If you decide not to take part, this will not affect the care and treatment you receive from your general practice. You do not have to take part and you do not have to give a reason for this. However, if you are willing to share your reasons with the researcher, this will be useful to us when we design other studies in the future.

If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. Even if you do decide to take part you can change your mind and be removed from the study at any time.

What are the possible benefits of taking part?

If you take part and are allocated to the intervention group, then you will receive visits and support from a nurse which may be in addition to your normal care and support. We cannot guarantee any specific benefits from this, but participating in research does

deliver wider benefits to society and others with a similar condition and will help us to determine how best to support people in the future.

What are the possible disadvantages and risks of taking part?

Participating in the research is not anticipated to cause you any disadvantages or discomfort. You will be asked to give some of your time as described earlier and this may be inconvenient to you.

What will happen to the results of the research study?

We hope the results will help us to design a large scale trial that will test further the HAPPI intervention. The results of this part of the research study will be written up and will form the basis of the lead researcher's PhD thesis.

Parts of the study will also be written up for the purposes of publishing the findings in health related journals and papers, or presentation at conferences. An additional short report of the research findings will be provided to the NHS Trust for distribution to participants. However, your data will always remain anonymous and your name will not appear on any of the results or write up. Results will also be made available on our website: https://www.plymouth.ac.uk/research/the-holistic-assessment-and-care-planning-in-partnership-intervention-study-happi

How will my information be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. The research team will publish the results of the study and other research documents, but you will not be able to be identified or identifiable in any reports or publications. Any data collected about you will be stored online in a form protected by passwords and other relevant security processes and technologies. Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties. These anonymised data will not allow any individuals to be identified or identifiable.

How will my personal information be used?

Plymouth University is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Plymouth University will keep identifiable information about you for 10 years after the study has finished. With your permission, we will retain your name and address for a maximum of one year after the study is complete so we can send you a summary of the study. The NHS sites will keep identifiable information about you from this study for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that

we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Cornwall Partnership NHS Foundation Trust will keep your name, NHS number and contact details confidential and will not pass this information to Plymouth University. Cornwall Partnership NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Plymouth University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Plymouth University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

You can find out more about how we use your information at https://www.plymouth.ac.uk/your-university/governance/information-governance or by contacting the University Data Protection Officer at dpo@plymouth.ac.uk.

What if something goes wrong?

If you have a concern about any aspect of this study, you should speak to the Lead Researcher, Helen Lyndon on 07919 891065, who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting Bridie Kent (Academic Supervisor) on 01752 586740 or NHS Patient Advice and Liaison Service on 01208 834620.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Plymouth but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who can I speak to if I want more information?

If you have any questions about this research please contact:

Helen Lyndon, Lead Researcher/Nurse Consultant

Tel: 07919 891065

Email: helen.lyndon@plymouth.ac.uk