

Information Sheet Consultees/Residents (Interviews)

(Version 1.1 20 Apr 2016)

Title of Study: **Falls in Care Homes (FinCH)**

Name of Researcher(s): xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Invitation

Your relative/friend is currently participating in the FinCH Study and you have already provided advice on their participation as they are unable to consent for themselves. As part of the Study, we would like to interview you and your friend/relative together about your experiences of the study. To enable us to do this we will need your consent to participate in an interview together with your advice as to whether your friend/relative would be happy to participate in this part of the study.

How do I find out more if I am approached to be a consultee?

Further information is available in the Department of Health's 'Guidance on nominating a consultee for research involving adults who lack capacity to consent'.

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_083133.pdf

This is also available from the research team, please ask if you would like a copy.

The following sections provide information about the study. This information is the same as would have been provided to your relative/friend.

What is the purpose of the study?

Many people, including those living in care homes, have falls which can lead to broken limbs, bruising and fear. The purpose of this study is to understand more about how we can help people stop falling over. We are going to be trying out a falls prevention intervention in a small number of care homes. This intervention is used at present with people living in their own homes but we don't know if it can be used with people in care homes. The intervention involves a number of different activities such as exercises, eating and drinking well, proper footwear, mobility aids and devices to alert carers to residents needing help. The care home staff are trained and supported by the NHS to deliver the intervention as normal day to day care.

Why have been chosen?

You and your friend/relative are being asked to take part in this study because your friend is a resident in one of the Care Homes where staff have been trained to use the intervention and, as part of the study, we would like to find out about both yours and your friend's experiences.

Do we have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form and also advise on whether you feel that your friend/relative would be happy to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or your friend/relative's care.

What will happen to me if I take part and what do I have to do?

You will be asked to take part in a one-to-one interview with a member of the FinCH research team.

The interview will last up to an hour and the interviewer will be an experienced researcher. The interview will take place at your friend/relative's Care Home. The interview will be audio-recorded so that it can be transcribed (typed-up) and then analysed.

At the interview you will be asked for your and your friend/relative's views on the falls prevention intervention. The interviewer will seek your and your friend/relative's views on what is good and not-so good about the intervention, including how you feel it is working and could it be improved. There are no right or wrong answers – it is your opinion that matters.

Expenses and payments

Unfortunately, we are unable to provide any payment to you for taking part in the research study.

What are the possible disadvantages and risks of taking part?

We do not envisage any harm from taking part in the study. If, at any time your friend/relative becomes distressed we will immediately stop the interview.

What are the possible benefits of taking part?

Your friend/relative will not benefit personally by participating in this study. However carers will be trained to use evidence based falls prevention interventions so residents might receive these interventions.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

If you remain unhappy and wish to complain formally, you can do this by contacting.

[Insert name of Local R&D contact details here]

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you and your friend/relative will be handled in confidence.

- If you join the study, the data collected for the study will be looked at by authorised persons from the University of Nottingham and the Norwich Clinical Trials Unit who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.
- All information which is collected about you and your friend/relative during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the care home will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.
- Your and your friend/relative's personal data (address, telephone number) will be kept for 3 months after the end of the study so that we are able to contact you about the findings of the study. (unless you advise us that you do not wish to be contacted) All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.
- If we consider anything you disclose about care provided that is harmful to your friend/relative or the residents we will be obliged to report to the Adult Safeguarding Committee. This is a joint NHS and Social Care Group.
- All audio recordings will be securely destroyed at the end of the study.
- We may use written quotations in presentations and publications but, these will be in a format whereby you or your friend/relative cannot be identified.

What will happen if we want to withdraw from the study?

Your participation is voluntary and you are free to withdraw both yourself and your friend/relative at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

It will take 3 years to complete the study. The findings will then be published in clinical journals. A summary of the study can be sent to any participant who requests one.

Who is organising and funding the research?

The research is being organised by the University of Nottingham, led by Professor Pip Logan, who is working with Norwich Clinical Trials Unit and is being funded by the National Institute for Health Research, Health Technology Assessment funding scheme.

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Who has reviewed the study?

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

Contact for further information

If you have any further questions about this study please do not hesitate to contact:

[Insert: Site Principal Investigator name]

[PI address and contact details]

and

[Insert: Local Researchers name]

[Local Researchers address and contact details]