

# Optional additional part of the 3D study - Patient Information Leaflet

## We invite you to take part in an optional additional part of the 3D study

- Thank you for considering this additional part of the study
- Before you decide whether to take part, please take time to read this leaflet carefully, and talk to others if you wish, to be sure you understand why this part of the study is being done and what it would involve for you.
- Please contact the research team if there is anything that is not clear or if you would like more information.
- This is an extra part of the study and taking part is optional.

# What is the purpose of the study

The aim of the 3D study is to help GP surgeries to manage and support people who have several long-term health problems. Some GP practices in this study are trying out new ways of organising care for patients with several long-term health problems and we need to understand how changes made by GP practices might affect people in this situation. We will interview up to 40 people who are taking part in the 3D study either individually or in a focus group to find out more about what you think about the services you have received. We will also observe and audio-record or video-record some consultations to find out what happens both in 3D consultations and in others that are not using the 3D approach and if possible interview you afterwards. Some extracts from these recordings may be used to help train doctors and nurses.

## Why have I been chosen?

You have been chosen because you have previously agreed to take part in the 3D study.

Taking part in this additional part of the study is voluntary. The covering letter we sent you with this information will tell you what it is we are inviting you to do. It is up to you to decide whether you would like to take part. We will contact you by phone a few days after sending the invitation. We can then provide you with further information about this part of the study and discuss with you what we would like you to do and whether or not you are happy to take part.

Whether or not you agree to this additional part, you will continue in the main trial part of the study unless you let us know that you want to stop. This means you will continue being asked to complete study questionnaires from time to time.

#### What will happen if I take part?

People in this part of the study will be asked to take part in one of the following options:

- 1. Audio-recorded interview
- 2. Focus group
- 3. Observed and audio-recorded, or video-recorded nurse/doctor consultation, possibly followed by an interview

You can choose whether you take part in any or none of these:

#### 1. Audio-recorded interview

If you decide to take part in the interview, you will be interviewed in person and we will discuss the care you have received from your GP surgery. The length of the interview is flexible, but will be around 45 minutes. The interview will be informal and will be arranged at a time and place agreed at your convenience. The interview will be audio-recorded but your real name will not be used in any written report about the interview or in published material.

#### 2. Focus group

The focus group will be a small informal group of about 6 people and we will discuss the care provided by your GP surgery. It will be arranged at a time and place agreed at your convenience. The length of the focus group is flexible, but will be around 90 minutes. The focus group will be audio-recorded but your real name will not be used in any written report about the interview or in published material. If you have been invited to take part in a focus group but would rather be interviewed on your own, please let us know and we will try to arrange that.

#### 3. Observed and audio-recorded or video-recorded nurse/doctor consultation

If you agree to have your consultation audio-recorded and observed, one of the researchers will sit in one of your consultations with a GP/nurse and observe how it goes and audio-record the consultation with your permission. If you agree to have your consultation video-recorded the doctor can record the consultation with your permission without the researcher being present. If you agree, we will arrange it with you and your practice. We will only record/observe you and your doctor/nurse talking together. Intimate examinations will not be recorded or observed and you can ask for the recorder to be switched off and/or for the researcher to leave the room at any time. All recordings will be carried out according to General Medical Council guidelines.

You can listen to or view the recording if you wish. If after seeing your nurse/doctor you do not want the consultation to be used, you can let us know and we will delete the recording immediately. The recording will be listened to by members of the research team to see how nurses and doctors communicate to patients and what happens at

these consultations. We ask permission to use anonymous quotes and observations for reports and short extracts for presentations to researchers and for training purposes.

For some audio-recorded or video-recorded consultations, we would like to interview the patient and the nurse/doctor after the consultation to find out their views of the experience. We may use the recording when we interview patients and doctors/nurses to help them remember what happened during the visit. Only people that took part in the consultation will listen to the recording. These follow-on interviews will also be audio-recorded.

# What if I don't want to take part in any interviews, focus groups, audio-recordings, video-recordings or observations?

It is entirely your choice whether to take part in any of these additional parts of the study. Please let us know. Your decision will not affect the care that you receive at your GP practice.

#### What are the benefits and risks?

We do not think there are immediate benefits to the participants being involved in this part of the study. However the findings will help us to understand what people think about the services provided by their general practice.

By taking part in this study you will help in the planning of services that general practices can offer people with several on-going health problems. This will benefit future patients.

Taking part will mean giving up some of your time to have an interview or attend a focus group. We will be asking you questions about your on-going health problems and your experiences. Some people might find this uncomfortable or upsetting. Taking part will also mean that you may have one of your 3D consultations recorded and/or observed which may make you uncomfortable.

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

You can stop the interview, recording or observation at any time and you do not have to continue. This will not affect the standard of care you receive. If you wish to listen to the recording of your consultation, you can arrange to do this at the University by contacting the researcher. You are free to withdraw from this additional part of the study at any time without giving any reason, but do not necessarily have to withdraw from the rest of the 3D study. If you do wish to withdraw from all parts of the study, then please let the research team know.

#### Confidentiality

Any information collected about you during this additional part of the study will be treated in confidence. Audio and video- recordings will be transcribed by a company approved of by the University of Bristol and made anonymous. Transcriptions and recordings will be stored

securely at the University of Bristol in accordance with University guidelines and the Data Protection Act. Apart from the research team, the only people who can see your information are from the NHS authority whose job it is to check the conduct of research in the NHS.

# Other Information about the study

The research is being run by the Centre of Academic Primary Care at the University of Bristol, with the Universities of Manchester and Glasgow. It is funded by the NHS National Institute for Health Research (NIHR).

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and approved by the South West (Frenchay) NHS Research Ethics Committee.

#### How to contact us

If you have any questions about this study, please contact:

<Local Researcher Name>

<Local Research Site Address>

Telephone: <Local Researcher phone number>
Email: <Local Research site email address>