



*lifelax*

## **A study about different ways of treating constipation in older people**

### **Diet and lifestyle versus laxatives in the management of chronic constipation in older people.**

We would like to invite you to take part in our research study. This study looks at the way that constipation in older people is treated by nurses and doctors.

Before you decide if you want to take part, it is important for you to know why the research is being carried out and what it will involve for you should you decide to join in please take time to read this sheet carefully - it answers many of the questions you may have. If you wish, you can show the leaflet to your family or friends and discuss it with them. If there is anything at all you are not clear about, or if you would like any more information, please ask one of the research team - our contact details can be found at the end of this sheet.

Please take your time to decide whether or not you wish to join this study - you don't need to make up your mind 'on the spot'.

Thank you for taking the time to consider the study.

### ***Who is doing this study?***

We are a team of researchers based at the Centre for Health Services Research at the University of Newcastle upon Tyne. This study is funded by the National Health Service. We will be working with GPs across England and Scotland.

### ***Why is this study being done?***

Constipation is a common and often bothersome problem in adults in the United Kingdom, particularly amongst those aged 50 and over. There are different ways in which doctors can treat it. Constipation can be treated by prescribing laxatives. It can also be treated by altering diet and lifestyle.

### ***What do you want to find out?***

We are carrying out the study because we need to know the best way to manage constipation in older people. To do this we need to compare the different types of treatment to see which one is best.

### ***How is this study being done?***

- **First** – we have recruited practices to the study (because you have this information sheet your surgery is taking part). Your practice will have been randomly selected to be in one of three groups. We will tell you more about these groups later in this leaflet.
- **Second** – we have helped practices to identify people, like yourself who can take part in our study.
- **Third** – doctors are inviting eligible patients to take part.

### ***How and why have I been picked?***

You have been chosen to take part because, according to your medical records, you have experienced constipation often enough and are in the correct age group for the study. We need about 1500 people with constipation, both men and women, aged 50 and over and will be selecting patients

from a number of general practices in England and Scotland

### ***What are the benefits to me for taking part?***

We hope that all the treatments on offer in the study will be of benefit to patients. However, there is no guarantee that an individual patient will get an immediate, direct benefit. We do hope that in the longer term our research will allow us to treat chronic constipation in a better way.

### ***Do I have to take part?***

No, it is entirely up to you whether you take part. We would like you to take your time, to read this information sheet and to think about the study. We would very much like you to help us, but if you decide not to take part, the care that you get from your GP's surgery will not be affected by your decision and no one will put pressure on you to take part. If you decide that you don't want to be part of the study you do not need to give us a reason.

### ***Can I say 'Yes' now, and change my mind later?***

Yes, you can. Even if you say 'yes' now you can leave the study at any time. You are not committing yourself to the study forever, and if you decide to leave you will not be asked for a reason.

### ***What are the three groups you mentioned before?***

As we said before, your practice will have been randomly selected to be in one of three groups. The three groups are:-

- 1) Your doctor will prescribe laxatives for your constipation.
- 2) Your surgery will give you standard, non-personalised dietary and lifestyle advice to help with your constipation.
- 3) Your surgery will give you personalised dietary and lifestyle advice, and you will be given ongoing help and advice to help with your constipation.

### ***Can I or my surgery choose the group we are in?***

No, it is not possible for you or your doctor to choose the group that you go into. This is because we have to make it as fair as possible for all practices and patients. Because none of the doctors can choose their favourite group there is an equal chance for all practices to go into each group. The group that a surgery is in is decided randomly (like the Lotto). Because there are three groups the surgery has an equal chance of one in three (33%) of being in a group. If you do not wish to be included in the study, you should tell your doctor. He or she will then treat your constipation in whatever way you and the doctor think is best for you.

### ***Will there be any lifestyle restrictions for me?***

There will not be any lifestyle restrictions as such for anyone taking part in the study. If you happen to be chosen for the Diet and Lifestyle group you will be offered advice on your lifestyle but whether you take it is entirely up to you. As with any treatment, please feel free to discuss any aspects of it with your doctor at any time.

### ***What about any side effects from the treatment?***

Because we are not trying out any new laxatives in the study, your doctor will be able to tell you of any known side effects for any of the laxatives they may prescribe. However, like any medicines, laxatives can have unwanted side-effects in some patients such as abdominal discomfort, bloating, flatulence etc. The likelihood and nature of these side-effects varies with the type of laxative but in general they are mild to moderate in intensity.

In the diet and lifestyle groups, you may notice a slight change in your bowel habits in the short term as it takes a while

for any changes you make to take effect. Again, if you have any concerns about any aspect of your treatment or constipation you can talk to your doctor.

### ***Is there another part to the study that I should know about?***

We will be asking some people to talk to us about their experiences of their time in the study. If we ask you to be interviewed for that part of the study, we will ask you to sign a consent form to say that you agree to be interviewed. Again, this does not tie you down. You will still be free to change your mind at any time and leave this part or the whole study.

### ***If I'm picked for the interviews, what will they be like?***

The meeting will take place wherever feels most comfortable to you (e.g. at home or in your GP's surgery.. If you have to travel from your home for the interview, we will pay your travel expenses. The interview will take about an hour and will be conducted by an experienced researcher. It will be taped so that the researcher can talk with you without having to make too many notes. This allows the interview to flow like a conversation and to be quite informal. Anything you say at any stage or any information you give us will be strictly in confidence. You can ask to have the tape turned off at any stage during the interview and you won't have to give a reason. Only people in the research team will ever hear the tape.

### ***What will happen next if I decide to take part in the study?***

If you would like to join the study, you will need to send the research team your contact details using the enclosed form and envelope. A member of the research team will contact you and answer any questions that you might have about the study. They will send you a copy of a consent form to sign. When you have signed and returned it to the study team they will arrange a convenient time to

call you on the telephone to ask you some questions about your general bowel health, constipation and medication. The research team will also tell you about your special study diary and how to complete it. We will ask everyone taking part in the research to fill in a diary to help us see which treatments are best.

After you have returned your consent form to the research team they will send a copy back to you along with a postal questionnaire. A copy of your consent form will be sent to your GP. We will also let your surgery know you are taking part in the study and need an appointment so your study treatment can begin. As we explained earlier, the treatment you receive at this appointment depends on the group your surgery is in.

Some people who were given diet and lifestyle advice will get a telephone call to ask about the diet and lifestyle advice they were given.

About three months after you join the study we will send you a questionnaire through the post. All we ask is that you would fill in the questionnaire and send it back to us. We will provide you with a stamped addressed envelope. We will ask you to fill in another questionnaire after six months and again after twelve months. Some patients will also receive a telephone interview to help in our economic evaluation in the study. You will be asked some simple questions about any costs you have had in connection with your constipation.

If when you start your study treatment, you decide that you don't want to take part in the research please tell the practice staff. They will let the study team know and we will destroy all of your study documents and paperwork including your consent form. No one will know what you said. Remember you don't need to give a reason why you don't want to take part.

### ***Will you need to see my medical records?***

In order to get all of the information about your constipation that we need, we will need to look at your notes at the end of the study. Again, all of this information will be kept private.

### ***Will I get paid for taking part?***

No, we are not paying anyone to take part in the study. Your doctors and nurses do not get paid for including you in this study. If you have to travel from your home for an interview at a later stage in the study, we will pay your travel expenses.

### ***Has anyone checked out this study to see if it is all right?***

When we applied to the NHS for money to do this research, our plans for the study were examined by other researchers to confirm that they are scientifically sound. The Multi-Centre Research Ethics Committee has reviewed the study. This committee is responsible for ensuring that all medical research going on in the area is ethical and fair to study participants like you.

### ***I have private health insurance. Do I need to tell my insurer if I decide to take part in the study?***

If you decide to take part in the study, it is most unlikely that it will affect any private health insurance that you may have. However, you should let your insurer know that you are taking part in the study.

### ***Will anyone else know I am in this study?***

Local GPs know that this study is going on. We have written to all practices to tell them of our work. Only your own GP's surgery will know that you personally are in the study. One issue that we need to draw to your attention at this stage is that the people who wrote some of the questions we will use in our research (Jansen Pharmaceuticals Ltd.) ask for our

data to be sent to them so that they can further refine their questionnaire. At this stage we make sure that no information that can identify any patient or doctor is sent. These data will be made completely anonymous and no individual or practice will be identifiable at any time.

### ***Will what I tell you be kept private?***

Other than staff in your practice, only the research team who will be running the study, and collecting and analysing information from study participants, will know who is in this study. We are all bound by a written code of confidentiality. This means that we must take great care to prevent anyone from outside the research team seeing any personal information about you, and we must not tell anyone else what you say. So all the information the research team has about you (e.g. from the interviews, questionnaires and examining your medical records) will be kept private. Any information about you which leaves the surgery will have your name removed so that you cannot be recognised from it. On your questionnaire, you are only identified by a number. Only people in our office will know who the questionnaire came from. Anything you tell us will be kept secret. We will not tell anyone what you have said unless you ask us to. If you decide to withdraw from the study at

any point all data and personal information collected will be destroyed.

### ***What will happen to the results from the study?***

At the end of the study, in 2006, the research team will write a report of the results for the NHS. After that, we will write articles about the findings for publication in the magazines that other health workers and carers read. In all the reports that we write, we will take great care that no individual patient can be identified. All the information the research team have about you will be kept private. If you would like a copy of the findings of the study, we will send them to you.

### ***How can I get more information about the study?***

Please feel free to contact a member of the research team if you would like some more information about the study, or if you have any questions you want answered. Our phone numbers are shown on the next page. You may contact us right through the study. It's best to call during office hours (9.00-12.30, 1.30-5.00) but we do have an answer machine switched on when we are out of the office. If you prefer to write to us, our addresses are also shown on the next page.

## The LIFELAX Research Team



The LIFELAX team (from left to right)

Dr Elaine McColl (Study Coordinator)

Mr Chris Speed (Trial Manager)

Mr Ben Heaven (Researcher doing interviews)

Ms Erika Tandy (Project Secretary)

LIFELAX office address

Centre for Health Services Research  
University of Newcastle upon Tyne  
21 Claremont Place  
Newcastle upon Tyne  
NE2 4AA