



lifelax

“What does it mean for me if I agree to take part in the study?”

“What are you going to ask me to do?”

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.

Some important questions answered

Welcome to LIFELAX. 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 doctors and nurses.

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. This short information sheet will give you a brief outline of the study, and explains why we need your help, and what we will ask you to do.

The Full Information Sheet that accompanies this one is more detailed and answers lots of questions about the whole study. It would be helpful for you to read it too. **You can call us anonymously if you have any further questions about taking part.**

Thank you for your time and the interest you have shown in our research.



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<i>Who is doing this study?</i>	The LIFELAX research team is based in the University of Newcastle. We work with GPs across England and Scotland.
<i>Why are you doing the study?</i>	Constipation is a common and often bothersome problem for older adults. There are different ways of treating it. We are trying to find out the best way of doing this.
<i>How are you going to do the study?</i>	We are trying three different approaches. One uses laxative treatment, two look at changing your diet and lifestyle.
<i>Why ask me to help in the study?</i>	Your GP believes our research to be worthwhile and is supporting us. According to your medical notes, you have been prescribed laxatives often enough to take part in the study.
<i>Do I have to take part in the study?</i>	No. It is voluntary. If you do agree to join then change your mind you can leave at any time. We will need you to sign a consent form to say you are happy to join, but even then you can drop out.
<i>What will I be asked to do in the study?</i>	A member of the research team will contact you and answer any questions you might have. You will be asked to sign a consent form. A convenient time will be arranged with you for you to talk to a member of the research team on the telephone. They will ask you some questions about your constipation. We ask everyone to fill in a daily diary about your bowel habits to monitor any changes during the study. We also ask you to fill in 4 postal questionnaires during the 12 months of the study. Some people may be asked about what it was like to take part in the study or get a telephone call to ask about the diet and lifestyle advice they were given. Just like before, this is voluntary and you don't need to take part.
<i>Can I choose my treatment?</i>	The treatment your surgery is asked to provide in the study was randomly chosen. This makes the study fair and equal. However, if you do not wish to continue in the study because you are not happy with the group your surgery is in, you should tell your doctor. They will then treat your constipation in whatever way you and your doctor think is best for you.
<i>Do I need to have any medical tests or examinations?</i>	No, not as part of our study.
<i>Will you need to see my medical records?</i>	Yes. This is because we need to see just how often you have been to see your GP during the study and what prescriptions you have had. This helps us to work out the cost of treating constipation.
<i>Will my records, diary and questionnaire answers stay private?</i>	Yes. We have to make every bit of information anonymous. Nothing you say can be traced directly back to you.
<i>Has anyone checked to see whether this study is safe?</i>	Yes. We have had it checked out by and approved by a Research Ethics Committee. It is sponsored by the NHS. We are not using any new or untried drugs. We have very strict rules to follow to make sure everything we do in the study is safe as it possibly can be.
<i>I want to know more. What should I do?</i>	The accompanying Full Patient Information Leaflet does tell you more about the whole study. If you can't find an answer to any of your questions in it, then please telephone Chris Speed.