WHAT ARE THE EFFECTS OF PILL BOXES?



An invitation to participate in a research project
Patient information sheet version 2 June 2012







What is a pill box?

It is a container divided into sections and labelled with days of the week and times of the day. Pills are put into the correct sections to help patients take their medication as prescribed by their doctor. Pill boxes are often filled by the pharmacy and are usually supplied weekly.

What is the project about?

We do not know whether pill boxes really help with taking medicines, so we are doing a small study to compare the effects of pill boxes with medication dispensed in the usual packaging. This will help to design a bigger study.

Why have I been chosen?

There are six medical practices taking part in this study. You have been chosen because you are a registered patient at one of these practices and you are over 75 years of age and taking three or more tablets per day.

Who is doing this research?

This research is funded by the National Institute for Health Research for the NHS. It is being carried out by researchers at the University of East Anglia together with the University of Aberdeen and Norfolk PCT.

What happens if I agree to take part?

Please note that we will not change any of your medicines and that your doctor will provide your care in the usual way. The study takes place in 3 stages.

Stage 1

This is to work out whether you are suitable to take part in the main study.

You will need to sign a consent form and complete a questionnaire which should take about 20 minutes.

The questionnaire asks for information about your health and wellbeing and your thoughts on medicines. Research has shown that pill boxes are used by patients with certain characteristics and so we would like to test the pill boxes with similar patients. The questionnaire will help us to identify whether you have the characteristics that we are looking for.

 You will then either receive a letter from us to let you know that we have received your questionnaire and that you do not need to do anything further or a letter informing you that we would like to visit you at home which is stage 2.



Stage 2

This is to look at how frequently you take your pills. We will not pass on information about your usual pill-taking behaviour to your doctor or pharmacist.

 You will be enrolled into the NHS repeat dispensing scheme so that your usual pharmacist can order and dispense your prescriptions for you in advance of you needing them.

This will help the trial run more easily. You can remain in the scheme or leave it at the end of the trial.

 We will telephone you to organize a home visit by a researcher at a time convenient for you. The research team are not a part of your GP practice.

You are welcome to have a carer or friend with you when we visit.

- We will remove your old stocks of pills (these will be returned to you later).
- We will provide you with a one-month supply of new pills.
- · After three weeks we will visit you and count your tablets.

After this we may ask you to take part in stage 3 of the study. If you are asked to take part in stage 3, we will let your GP know that you are involved in the study. If you are randomly selected to get a pill box, we will give you a choice of 3 pill boxes and ask you to select the one you most prefer.

Stage 3

This is to find out whether pill boxes really do help.

- Your usual medication will be supplied to you by your usual pharmacy.
- You will receive your medicines either in normal packaging or in a pill box for a three month period.

These will have a film attached to them which will allow us to electronically monitor when you take your tablets.

- You will either receive your medication on a weekly or monthly basis.
- If your medication is usually delivered to you by your pharmacy, this will continue and if your medicine is supplied on a weekly basis it will be delivered to you by the pharmacy.
- You will be given simple tests of eye sight, hand coordination and memory.
- We will ask you to complete a short questionnaire about your health and wellbeing which should take about 15 minutes to complete.
- At the end of the 3 months we will ask you to complete the same questionnaire again which will also ask about your satisfaction with your method of medication supply. This questionnaire should take about 20 minutes to complete.
- If you have told us that there is someone who helps you
 with organizing your medicines, we will send them a questionnaire to ask them whether the way that your medicines
 are packaged has made a difference to them.

What are the benefits of taking part?

We cannot promise that the study will help you but the information we get from this study will help the NHS to make decisions about how to spend its money and whether to spend more on pill boxes.

Are there any disadvantages to taking part?

We do not think there are any major disadvantages in taking part, but you will need to alter the way you take your pills if you get a pill box.

You will also be giving up some of your time for researcher visits and for filling in questionnaires.

What about confidentiality?

The only information taken from your medical and pharmacy records will be: age, details about your medical conditions and prescribed medications. We will use your NHS number to find out whether you have had any hospital visits whilst taking part in the project. Any information we collect will be kept in a secure location at the university.

We will not share information with others except where there is strong concern for your safety or that of others. In that event, we may need to talk to other relevant professional organizations.

What happens when the project ends?

The information will form part of a doctoral thesis and may be published in a medical journal but will not include any names or personal details that would allow you to be identified. The information may also be used by the NHS to help them decide whether or not to do a larger study to test the effects of pill boxes.

You may be invited to attend a group discussion for you to give us more detail about your experiences of being involved in the study. If this happens you do not have to take part if you don't want to.

If you were given a pill box and would like to continue to get a pill box you will need to speak with your usual pharmacist who will arrange for you to be assessed to find out whether the NHS will pay for your pill box.

Finally, if you would like a summary of our findings please let us know so that we can arrange for you to receive a copy.





What if I want to take part?

Please complete the enclosed consent form and questionnaire and return them to us in the pre-paid envelope provided.

What if I change my mind?

If you change your mind, you are free to withdraw from the study at any time without providing a reason. All you need to do is telephone us, send us a letter or e-mail using the information on the back of this form.

What if there is a problem or I want more information?

Please telephone the project manager (Clare Aldus) on who will be pleased to provide you with further information.

If you have concerns about this study or for independent advice about being involved in research, contact the Patient Advice and Liaison Service (PALS) on

This project is funded by the National Institute for Health Research, Health Technology Assessment (NIHR HTA) programme (project number 09/34/03).