PATIENT INFORMATION SHEET

STUDY OF TREATMENT FOR AGITATION IN PEOPLE WITH MEMORY PROBLEMS

We are carrying out a research project to find out about the best way to help people who have agitation and memory problems. We will use the results to try to improve the treatment and care of people with such problems. We are inviting people with memory problems who have problems with agitation to take part.

Your doctor believes that you have the type of symptoms of agitation and memory problems that this study is designed to look at and has referred you to the research team. There is a wide choice of medicines available to treat symptoms of agitation, but it is not clear which treatments are best in those people whose who have dementia. We are asking you and _____ [name of legal representative] whether this is something you would like to do. If you would rather not take part, that is up to you and you don't need to give a reason.

What will happen to me if I take part?

A researcher will visit you and ask you some questions about how you feel, your memory and any difficulties that you might have. If you have the sort of health problems that the study is designed to investigate then you will be invited to take part in the study.

You would be allocated, by chance, to one of two groups – one group will receive mirtazapine (a widely prescribed medication), and a second group will receive a placebo. A placebo is a "dummy treatment" which looks like the medicine but contains no active medication. In this way, we will be able to work out what works best.
You would have a one in two chance of receiving an active treatment.

There is reason to believe that the medicine may be helpful, but we do not know if the medicine will work in those with agitation and memory problems. This is what the study is designed to investigate.

You will also need to have routine blood tests and a recording of your heart (an ECG test), to check it is safe for you to take the trial medicine.

You will continue to receive care from your doctors and other health and social services in the usual way.

You would take 1 tablet for the first 2 weeks, 2 tablets for the second 2 weeks, and 3 tablets for the next 8 weeks. These would be taken once a day, in the evening. Neither you nor we would know which treatment you are on until the end of the study, although your doctors could find out if they needed to know, because of an emergency.

The researcher will visit you twice more, 6 and 12 weeks after the first meeting to ask you these questions again to see if things have changed. This will take around an hour each time. You will also need to have the same blood and heart tests once you finish taking the study tablets.

We will also ask _____ [name of carer] as a family member, friend or carer that knows you well about how they see your health and quality of life and how this changes over the trial. We will contact them at the same 3 occasions as we talk with you and will also contact them 4 weeks after you stop taking study tablets and 6 and 12 months after the start of the study by telephone. These calls are to see how things are with you in the longer term.

If you would like to talk to someone about how you feel after taking part, you can speak to one of our team (contact details below), or ring the Alzheimer's Society National Dementia Helpline on 0300 222 1122. It is usually open 9am-5pm Monday to Friday and Saturday and Sunday 10am-4pm.

Will my taking part in the study be kept confidential?
Yes. All interviews are confidential and you will not be identified in any report or publication.

If anyone tells us that they or someone else is being harmed we will ask their permission to tell an appropriate responsible person. We respect confidentiality but cannot keep it a secret if anyone is being harmed.

What are the possible benefits of taking part?
We cannot promise that the study will help you, but the information you provide us with may lead to improvements in the treatment of people with memory problems who also suffer with agitation. It may be that you will

benefit from the treatment which is being offered as part of the study. Your cooperation will be invaluable for us to help others suffering from similar symptoms to you, both now and in the future. The study's findings will help doctors to know which treatments should be used.

What are the potential disadvantages and risks of taking part?
The medicine is usually well tolerated, but may cause side effects. These are usually mild and tend to reduce by themselves after 2 or 3 weeks. The most common side effect of mirtazapine is a mild stomach upset which usually resolves over a few days, some also gain a little weight. Some may feel drowsy after taking it which is why we are giving the medication at night.

Blood tests are being taken for your safety but may cause you some discomfort or inconvenience.

What if there is a problem?
If you take part, a 24-hour telephone number will be provided for your doctors in case of medical emergencies. If you would like to complain about the study, you can ask [name of legal representative] _____ to help you.

Whom do I contact for information or advice?
The name of the individual who has organised and is co-ordinating the study is Professor Sube Banerjee at Brighton and Sussex Medical School, University of Sussex.

The name of the doctor responsible for entering you in the study is Professor Gill Livingston (Tel: 0207 679 9435, Email: g.livingston@ucl.ac.uk)

Thank you for considering helping with this.