LEGAL REPRESENTATIVE INFORMATION SHEET

STUDY OF TREATMENT FOR AGITATION IN PEOPLE WITH MEMORY PROBLEMS (SYMBAD)

You are being invited to act as a 'legal representative' for ________________ because s/he is unable to make a decision for her/himself. You are being asked to advise the researcher about this person's wishes and feelings and whether they would have wished to join this research. Before you decide, it is important you understand what being a legal representative means for the purposes of this trial, why the research is being done and what it will involve. Please take time to read this information carefully and talk to others about the study if you wish. Ask us if anything is not clear or if you would like more information. Take time to decide whether you wish to be a legal representative.

What does it mean to be a legal representative?

A legal representative is someone who knows a person who doesn't have capacity well and is willing and able to offer an opinion on what that person's wishes would have been if they were still able to decide themselves whether to take part in this research study. You do not have to act as a legal representative if you do not want to. If you decide to act as legal representative, you will be asked to sign a legal representative consent form. If you think that this person would not have wanted to take part in this research study, then the researchers will respect this. Please remember that you are not being asked for your personal views on the research but only what the named person's wishes would have been, were they being asked to take part in this research. Think about the broad aims of the research, the risks and benefits and what taking part will mean for this person. At any stage, you can advise the researcher that in your opinion the person would no longer wish to remain in the study.

Why have I been asked to be a legal representative?

You may have been asked to act as this person's legal representative because you know the patient personally, as a friend, partner, or relative, and they would trust you to help with this decision; or, you may be a member of the individual's care home or other staff, and you have the patient's best interests in mind.

About the study

Your relative/friend/patient has been invited to take part in a research study that aims to generate new evidence on the treatment of agitation and aggression in dementia. If they take part, we will also need you to provide information to the researcher. This Information Sheet explains more about the study, how your relative/friend/patient will be involved, and what we would like you to do as a legal representative. Before you decide whether you are happy to take part in the study and willing to provide information to the researcher during the study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to act as legal representative.

The role of legal representative and carer in this study

In this study we will be obtaining information from the person with dementia and also a carer who knows him/her well. In some cases the carer will also be the legal representative so it may be that you will be acting as the carer who knows the person with dementia well and who is contributing information about the patient for the research as well as being their legal representative. In this instance you will be asked to sign consent forms agreeing to both roles. This form relates to the role of the legal representative. There is a separate form that relates to the role of carer in this project and you will receive this if you are acting as a carer as well as a legal representative.

Part One of this sheet explains the purpose of the study and what will be asked of the relative/friend/patient/ you are advising, if you agree that they take part.

Part Two of this sheet gives further information on how the study will be carried out.

Part One

What is the purpose of the study?

We are trying to establish what the best treatment is for the management of agitation and/or aggression in people with dementia. It is quite common for people who suffer from dementia to have such symptoms and they can cause problems. 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 who have dementia.

Why was my relative/friend/patient invited to take part?

The clinician who has seen your relative/friend/patient believes that he or she has type of symptoms of agitation and/or aggression and memory problems that this study is designed to look at and has referred him/her to the research team.

Does my relative/friend/patient have to take part?

No. It is entirely up to you and your relative/friend/patient to decide if they would like to take part in the research. The assessment carried out has shown that the person with dementia does not have the capacity to consent to take part for themselves so we have approached you as their legal representative to consider if in your view they want to take part in the above study if they could decide. If you decide that they would wish to take part in the research they will be given an information sheet to keep and you will be asked to sign a legal representative declaration form.

The participation of the person about whom you are giving advice is voluntary and you are free to advise they should be withdrawn, at any time, without giving any reason, without their medical care or legal rights being affected.

What would be involved if my relative/friend/patient takes take part?

The study lasts for 12 months and is divided into three parts: (1) the consent and assessment part which will be completed in one or two visits, (2) the treatment part which takes 12 weeks and then (3) final questionnaires at 6 and at 12 months that we request from the patient’s carer by telephone.

During the 12 months your relative/friend/patient will be asked to complete a series of questionnaires, as will a carer who knows him/her well. As noted above, it may be that you will be acting as the carer who knows the person with dementia well and who is contributing information about the patient for the research as well as being their legal representative. In the first 2 parts, we will usually make three or four visits to see your relative/friend/patient and their carer and then we will talk to the carer on the telephone on three other occasions. The visits will usually take place where your relative/friend/patient lives unless somewhere else is more convenient for him or her. They may also need to attend the local hospital for their blood tests. The researcher will spend about an hour with each of the person with dementia and the carer during these visits.

The first meeting will include an assessment of agitation and other behaviours, made by a member of the research team. If this indicates that your relative/friend/patient has the sort of symptoms the trial is designed to look at, and if there is no other reason why they should not take part, then they will be asked to take part.
Your relative/friend/patient will need to have some routine blood tests to check it is safe for them to receive study medicine.
They will also need to have a tracing of their heart (an ECG) to check it is working normally. If they have had any of these tests in the last month and we are happy with the results they will not need to be repeated.
It may be possible for them to have both these tests at home or they might be asked to attend the local hospital. This depends on the community nursing facilities in your local area and we can advise you of this.
The study is planned as a randomised study. In the second part of the study, your relative/friend/patient will be allocated randomly to one of three groups – one group will receive a medicine called carbamazepine (this is a widely prescribed medication for people with seizures and also those with depression), a second group will receive mirtazapine (a widely prescribed antidepressant), and another group will receive a placebo. A placebo is a “dummy treatment” which looks like the genuine medicine but contains no active ingredient. In this way, we will be able to compare the effects of having either of the drugs against the placebo. Your relative/friend/patient will have a two in three chance of receiving a real medication. While there is reason to believe that the two drugs may be helpful, we do not know whether these medicines work to reduce agitation and aggression in dementia. This is the question that the study is designed to investigate. Your relative/friend/patient will not be able to choose which medication they will receive in the study. The decision as to which group they will be put in will be made by a computer. This is to try to make sure that the groups of people taking the different medications are as similar as possible to start with.

We are comparing the two medications we are studying with placebo rather than with those that are most commonly used currently (antipsychotic medication). This is for two reasons. First, because there are well established concerns that antipsychotic medication may not be very effective at treating agitation in dementia, with a positive effect from the medication in at most one in five people with agitation in dementia. Second, because people with dementia have an increased risk of experiencing serious side effects when they are prescribed these medications. This is why we are trying to find out if the medications we are investigating in this study are effective and safe.

Your relative/friend/patient will be asked to take one tablet for the first two weeks of treatment, two tablets for the second two weeks, and three tablets for the remaining 8 weeks of treatment in the study. These will be taken once a day, in the evening. Neither you, the person with dementia nor the researchers will know whether they are taking a ‘dummy treatment’ or one of the medications until the end of the trial, although their doctors could find out if they needed to know because of an emergency. They will continue to receive care from their doctors and other health and social services in the usual way.

What are the possible benefits of taking part?
We cannot promise that the study will help your relative/friend/patient, but the information provided may lead to improvements in the treatment of people with memory problems who also suffer with agitation and/or aggressive behaviours. It may be that they will benefit from the different treatments which are being offered as part of the study. Your relative/friend/patient’s cooperation will be invaluable for us to help others suffering from similar symptoms, both now and in the future. The study’s findings will help doctors to know which treatments should be used. You will receive no

payment for participating in this trial, however travel expenses for your relative/friend/patient and their carer will be reimbursed.

What are the potential disadvantages and risks of taking part?
It will take up time. Your relative/friend/patient may need to travel to a hospital for blood tests. (Your researcher can tell you whether this will be necessary). Blood tests are being taken for their safety but may cause some discomfort or inconvenience.
These medicines are usually well tolerated, but may cause side effects. These are usually mild and tend to reduce by themselves after two or three weeks. The most common side effect of mirtazapine is a mild stomach upset which usually resolves over a few days. Some patients taking mirtazapine also gain a little weight. Some may feel drowsy after taking it which is why we are giving the medication at night. The most common side effects of carbamazepine include drowsiness, dizziness and headaches; rarely it can cause a rash and blood problems. We have attached patient information leaflets on carbamazepine and mirtazapine for detailed information.

There is also a small possibility that your relative/friend/patient may experience some mild emotional distress during or after discussions with the member of the research team. This can happen to anybody at a health assessment where attention is drawn to problems they might have with mood and memory. The member of the research team will be able to offer support during the visit if they are upset, but may also contact the doctors or care workers who normally provide care for them, if you or they feel they need further support. You may also find it helpful to ring the Alzheimer's Society National Dementia Helpline on 0300 222 1122. The Helpline is usually open from 9am to 5pm Monday to Friday and on Saturdays and Sundays from 10am to 4pm.

What happens when the research study stops?
At the end of the trial the doctor who normally provides your relative/friend/patient’s care will decide with them and you as appropriate what medication if any it would be helpful to prescribe.

What if there is a problem?
If your relative/friend/patient participates in the trial, a 24-hour telephone number will be provided in case of medical emergencies, when it may be necessary to inform your relative/friend/patient’s doctor which trial medicine they are receiving. If this becomes necessary, they may be withdrawn from the trial, and offered whatever treatment is appropriate.

If you have any complaint about the way you or your relative/friend/patient have been dealt with during the study, this will be addressed by the research team. Detailed information on this is provided in Part 2.

What will happen to my answers?
The information given will only be used for the study, and will be stored and analysed anonymously, using code numbers rather than names or other identifying details.

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 your relative/friend/patient in the study is___________________________
[insert local recruiting PI name]

This completes Part One of the Information sheet.

Part Two

Will my and my relative/friend/patient's taking part in this study be kept confidential?
Yes. The information that is gained during interviews and from questionnaires will be kept confidential. When processing and storing information, we will comply with the Data Protection Act 1998 to protect your and their confidentiality. During the study, their information will be labelled or 'coded' with a participant number, not their name. All data will be stored securely. You will have a right to check the accuracy of data held and to correct any errors.

Only a small number of researchers will have access to your relative/friend/patient's personal information (e.g. name, address, telephone number) to be used for contact purposes only (e.g. to arrange visits). All personal information will be stored separately to study results in a secure location.

By agreeing that they can take part in this research, you will be agreeing to your relative/friend/patient's questionnaire information being seen by other people who check that the research has been conducted correctly. These people include the Department of Health (the funders of the research), ethics committees, regulatory authorities and the research team at the clinical trial unit who are carrying out the research. Anyone who works with participants' information agrees to hold it in confidence.

Everything you and your relative/friend/patient says/reports is confidential unless they tell us something that indicates they (or someone else) are at risk of harm. We would discuss this with you and them as appropriate before telling anyone else.

What will happen to the results of the research study?
When we have collected all the results for this study we will analyse them and then publish and present the results. Your relative/friend/patient will not be identified in any publication or presentation.

What if relevant new information becomes available?
Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, the research team will tell you about it and discuss whether you want your relative/friend/patient to continue in the study. If you decide not to advise that they carry on, the research doctor will make arrangements for their care to continue. If you decide to advise their continuing in the study you may be asked to sign an updated legal representative declaration form. Also, on receiving new information the research doctor might consider it to be in your relative/friend/patient's best interests to withdraw them from the study. He/she will explain the reasons for this and arrange for care to continue. If the study is stopped for any other reason, you will be told why and continuing care will be arranged.

What will happen if I decide it is not in my relative/friend/patient's best interest to carry on with the study?
If you decide this then please contact a member of the research team. They are free to stop trial medication at any time. We do ask that they continue to provide information for the trial, even if they stop medication but if you do not wish your relative/friend/participant to provide any more information and withdraw completely from the research then you are free to do this too.

All data collected up to the point of withdrawal from the research will be kept for analysis and publication purposes.

What will happen if I don’t want to carry on with the study in my role as legal representative?

If you would no longer would like to carry on as legal representative then please contact a member of the research team.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with Prof Sube Banerjee (Chief Investigator for the study) (01273 678472) who will do his best to answer your questions. If you remain unhappy and wish to complain formally about any aspect of the way you or the person you are advising us about have been approached or treated during the course of this study, you may contact the Research Governance Sponsor of this study, the University of Sussex College through their Research Governance Office (Email: rgoffice@sussex.ac.uk Tel: 01273 872748).

In the unlikely event that your relative/friend/patient is harmed due to our negligence, you are encouraged to approach us through the research team. Normal legal processes are also open to you. Independent advice can be sought through the University of Sussex Research Governance Office (Email: rgoffice.sussex.ac.uk, Tel: 01273 872748).

The Universities of Brighton and Sussex have insurance in place to cover their legal liabilities in respect of this study. The normal National Health Service complaints mechanisms will be available to you.

Involvement of your relative/friend/patient’s general practitioner (GP)

Their general practitioner (GP) will be notified of their participation in the trial (with your agreement). Other medical practitioners not involved in the research but who are involved in their treatment will also be informed of their participation in the trial, where appropriate.

What if I or my relative/friend/patient would like to find out the results of the study?

If you or your relative/friend/patient would like to learn more about the findings of the study, please ensure that the appropriate box on the consent form is ticked. At the end of the study (mid 2019), we will post you and them a short summary of the results for you and your relative/friend/patient to keep. We will also send you and your friend/relative regular newsletters throughout the study to keep them up to date with our findings. These will describe group findings and will not include any individual information.

Who is organising and funding the research?

The trial is being organised by the University of Sussex with the help of the Clinical Trials Unit at Norwich Medical School. It is funded by the Department of Health.

Who has reviewed the research?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Hampshire A Research Ethics Committee, for the trial to proceed in the NHS.

Contacts for further information

If you require any further information about this study then please do not hesitate to contact [local PI name] on ________________.

Thank you for taking the time to read this Information Sheet, and for considering taking part in this study. If you wish to participate you should retain this information sheet.