

Information Sheet

Volunteering for research into dementia

Introduction

This information sheet is for people with dementia or relatives of people with dementia who are considering taking part in research. It looks at the information you should know before you decide to participate (or to agree to your relative participating).

Consent

A considerable amount of research is aimed at the early phases of dementia, when someone with dementia may be able to give consent to participation. However, later in the illness, this may not be possible. Relatives' consent is required when someone with dementia is unable to give informed consent. Two important principles should be followed:

1. Whatever the degree of dementia, the person with dementia should be made aware, as far as possible, of what will be involved.
2. If the person with dementia is not willing to participate then he or she should not be recruited to the research project (even if it is a relative's wish that the person takes part).

Medical research into dementia can be divided into two basic themes:

1. Scientific research which will advance our understanding of dementia, particularly its causes, its effects and its diagnosis.
2. Research into treatment and management of dementia, involving testing of drugs, therapies etc.

Scientific research

You should be aware that the individual who participates will not directly benefit from this research. However, this kind of research is essential to the later

development of treatment or methods of prevention and people with dementia a number of years ahead may benefit. Many people with dementia are pleased to volunteer for this kind of research.

Treatment and therapies

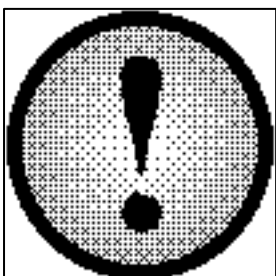
There is a danger that people with dementia or their relatives may come forward for research into treatments and therapies in the belief that they will be first in line for a 'wonder-drug'. They are almost certain to be disappointed. There have been drugs developed which have provided a complete cure for specific diseases or medical conditions. But the changes in the brain of a person with dementia are very complex and no medical researcher believes that there can be such a simple cure. However, drugs may provide effective treatment or alleviate symptoms. This is why there is so much research going on at the moment into developing drugs.

Many drug trials turn out to be a failure in terms of treatment, but they still help to advance scientific understanding by closing one avenue of research or eliminating one theory. This will eventually help others.

Volunteering

When volunteering for research there are a number of things that you should be aware of. The most important is that it is research. It is quite possible that you may hear of some remedy or therapy which is being tested. But the objective may be to promote its use rather than research its effectiveness. That is not to say that it would be wrong to participate but you must be sure of the motives of those who are doing the testing.

Medical research will normally be



carried out by a hospital or university. It will be approved by an Ethics of Medical Research Committee set up by the Health Board. The Committee will have checked that it is ethically right to ask people to participate in the research. The Committee includes non-medical members to ensure that the interests of individuals rather than 'medicine' are safeguarded.

An information sheet should be available, which tells you about the research organisation, the reason for the research and what would be involved for volunteers.

The following is a checklist of questions to which you should have answers before agreeing to participate in the research. If there is an information sheet it should have most or all of the answers, but you should still ask to talk to the person heading the research.

1. What is the purpose of the research?
2. Has the research been approved by a medical ethics committee?
3. What does the research involve for people who take part?
4. Will people taking part benefit from participation?
5. Will you (or your relative) be given injections or drugs?
6. Will it involve discomfort?
7. Will it cause distress or anxiety?
8. Will there be any side-effects or risks and how serious could they be?
9. How long will it go on?
10. Where would you (or your relative) have to attend and how often?
11. Might people taking part be in a group used for comparison ('control group') and receive a placebo (dummy pill) or no treatment?

12. If the research involves treatment, can participants continue with the treatment after the end of the trial if it has benefits for them?

13. What will you be told after the research is completed?

14. Will expenses be paid?

When you meet someone from the research team they should be able to give satisfactory answers to your questions. It is almost certain that they will be very enthusiastic and optimistic about their research and will want you to become involved. We would not wish it to be any other way, but don't let this push you into making a quick decision.

Go away; think about the information and answers you have been given; tell your GP or hospital consultant; then finally, having taken time to think about it - make up your mind. An important question for relatives making the decision on behalf of someone with dementia is whether he or she would wish to participate if he or she could understand what was involved.

If you decide to become involved in medical research you will be asked to sign a consent form. This is really just the researcher getting permission from you to carry out certain procedures. It does not mean that you (or your relative) have given up any legal rights. Also it does not force you to continue with the research if you wish to stop for any reason. Anyone can drop out at any time, and there will be no implications for him or her.

If you have a complaint about the research take it up initially with the head of the research. If you are not able to get a satisfactory answer take the matter up with the Health Board, or talk to Alzheimer Scotland - Action on Dementia about the problem.

When the research is over you will very





likely want to know what it revealed. There is no obligation upon a researcher to share their findings with subjects or their relatives. Usually, however, they should be prepared to do so, or they may promise to send you a copy of a report or published paper (this could take some time - perhaps years).

If the research involved treatment then sometimes it will be obvious whether the treatment helped, made no difference or made matters worse. But the researchers will not normally be able to provide information on the response, effect or outcome in individual cases.

The above discussion has mainly focused on medical research. But the same principles apply to other research, for example, social research, nursing and methods of care.

This sheet was prepared with assistance and advice from Dr. Robert Hunter, Dr. George Masterton and Rev. Senespleda



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HOUR

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