



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 agree to your relative participating).

The term research means different things to different people, but it is essentially about finding out new knowledge that could lead to changes in treatment, policies and care.

Medical research into dementia can be divided into three basic themes: **cause, cure, and care**

Cause: Scientific research at cellular level which will advance our understanding of dementia, particularly its causes, its effects and its diagnosis. This is done in laboratories.

Cure: Clinical research into treatment and management of dementia, involving testing of drugs, therapies, etc.

Care: Social science research into the best ways of caring for and supporting people with dementia, their partners and families.

Cause

Scientific research

You should be aware that people who take part in this type of research are unlikely to benefit from it themselves. However, scientific research is essential to the understanding of how the disease develops and to the development of new treatments and methods of prevention. This may benefit people in the

future. Many people with dementia are pleased to volunteer for this kind of research if they think it will help others.

One way you can help with scientific research is through tissue donation

Brain tissue donation

Much of our current understanding of Alzheimer's disease and other types of dementia, as well as advances in treatment, has come through looking at brain tissue generously donated by individuals and families over the years.

It cannot be underestimated how valuable donated brain tissue is. Dementia research needs brain tissue from people with dementia and brain tissue from people who have not had the illness, for comparison.

One way to significantly increase the value of your donated brain tissue is by registering your interest in donating during life. This allows the brain tissue bank to collect important information about you.

You can record your wish to donate your brain tissue after you have died by including it in your will and in any advance statement or "living will" you have drawn up. You should discuss this with your family so they know your wishes, as it will be your next of kin who will have to consent to the removal of brain tissue after your death. This will go a long way to ensuring your wishes are honoured

Donating brain tissue in Scotland

The Alzheimer Scotland Dementia Research Centre, in partnership with the University of Edinburgh, are developing and maintaining a Scottish Brain Tissue Bank. This is the first dementia-specific brain bank in Scotland. To find out more about brain tissue donation, please call the Dementia Helpline on 0808 808 3000.

You can also register your details with the Scottish Dementia Clinical Research Network (see section on Volunteering for research)

Cure

Treatment and therapies

Many people may volunteer for trials in the belief that they will get access to new treatments. In some trials this may be the case, but there is no guarantee that people will receive the new treatment or benefit from it even if they do.

Clinical trials are research studies which compare a new or different type of treatment with the best treatment currently available. They test whether the new or different treatment is safe, effective and/or any better than what already exists. No matter how promising a new treatment may appear during tests in a laboratory, it must go through clinical trials before its benefits can really be known.

Many trials are often referred to as **Randomised controlled trials (RCTs)**. An RCT compares two groups of similar people, an **experimental** group that receives the new treatment (this may be a drug or another type of treatment) and a **control** group, who receive usual treatment, which might include medicines routinely prescribed or a **placebo*** (dummy) tablet. The control group allows researchers to see whether the treatment they are testing is any more or less effective than usual or standard treatment.

In a randomised controlled trial, the decision about which group a person joins is random (i.e. based on chance, the toss of a coin). In many trials the allocation process is done by a computer, and the researcher is unable to influence the outcome. This ensures that the two groups are as similar as possible. This is important because it means the researcher can be sure that any differences between the groups are only due to the treatment.

Randomised controlled trials are considered to be the most robust scientifically.

***Placebos**, dummy tablets, are sometimes used when there is no similar treatment to compare it with. You may also hear the word **blind**, in these types of trials. This means that the participant, and in some cases, the researcher is 'unaware' of which group they have been allocated, in order to prevent any bias. This ensures that all participants are treated equally.

Many drug trials turn out to be unsuccessful 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.

Care

Social research

To most of us, the word research means people in labs with white coats and doctors doing trials to test new drugs, but there are other forms of research which can benefit people with dementia, their partners and family members.

Social research studies may involve filling out questionnaires, attending a face to face interview, or a focus group. Researchers may be looking for 'quantitative' information, e.g. how many people, how many times, or 'qualitative' information, e.g. people's feelings or experiences of things.

People's experience of events in their life, particularly ill health, is invaluable to researchers and is often used in service planning and policy development.

This type of research is covered by the NHS Research Governance Framework for health and social care.

Consent to take part in research

Although people with dementia may want to take part in medical or other research, their consent must not be taken for granted.

Before dementia starts, and at the earlier stages of the illness, people will be able to take such decisions for themselves, and may be able to consent to research. They may wish to show their general willingness to participate in research by making an advance statement to say so or by granting someone a welfare power of attorney with the power to consent to research on their behalf. Later in the illness this will become difficult or impossible.

The Adults with Incapacity (Scotland) Act 2000 sets out clear rules for what medical, surgical, psychological, nursing or dental research can be done using people who cannot consent:

- Under the Act, research involving people unable to consent to take part can only be done if it could not be carried out with people who can consent.
- The research must be about the cause, diagnosis, care or treatment of the person's illness.
- It must be likely to produce a 'real and substantial benefit' for the person, or to bring understanding that will help other people with the same condition.
- The research must be approved by a special Ethics Committee and must involve no more than minimal foreseeable risk or discomfort.
- The person should be withdrawn from the research immediately if at any time

he or she objects in any way or appears to suffer discomfort.

- The research cannot involve anyone who is unwilling to take part.
- The researchers must get consent from the person's welfare attorney or guardian, if there is one, or else from the nearest relative. If it is not possible to get this consent it will not be legal for the person with dementia to participate.

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, he or she should not be recruited to the research project (even if it is a relative's wish that the person takes part).

Giving consent 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.

Volunteering for research

When you volunteer for any research, you should be provided with an information sheet – this will vary in length and detail depending on the type and complexity of the research. You should take time to read it carefully as it will tell 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. The information sheet should provide most of the answers, but ask to talk to the person heading the research if you are unsure of anything.

Questions

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? (extra visits/blood tests/injections, etc.)
4. Will people taking part benefit from participation?
5. How long will it go on?
6. Where would you (or your relative) have to attend and how often?
7. Does the person taking part in the trial have to have a carer to take part?
8. Might people taking part be in a group used for comparison (**control group**) and receive a placebo (**dummy pill**) or no treatment?
9. If the research involves treatment, can participants continue with the treatment after the end of the trial if it has benefits for them?
10. What will you be told after the research is completed?
11. Will expenses be paid?

When you meet someone from the research team they should be able to give satisfactory answers to your questions.

Rather than rush in to volunteer for the research, you should take some time to think about the information and answers you have been given. You may want to speak to your partner or family, your GP or hospital consultant before making 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 have any complaints 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 your local NHS Board, or talk to Alzheimer Scotland's Dementia Helpline (0808 808 3000) about the problem.

What happens after the research?

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. In some cases this may take years, especially if the research is being carried out in several centres, or in several countries.

If the research involved treatment, 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.

In trials of a new treatment, it is not always possible to continue with the treatment after the trial is completed as the treatment may not yet be licensed, but you should be made aware of this at the beginning.

Ethics in research

All trials conducted in the UK, must have been reviewed and approved by an **Ethics Committee**.

Ethics are a set of principles that guide researchers who are carrying out research with people. Ethical principles are designed to protect the safety, dignity, rights and well-being of the people taking part.

The job of an ethics committee is to make sure that the researchers abide by these principles. The committee will consist of health

care professionals and members of the public, 'lay' people. There is a specific ethics committee in Scotland that deals only with trials in persons who may lack or may lose capacity during the trial. (i.e. unconscious patients or patients with a dementia)

Scottish Dementia Clinical Research Network

In 2008, NHS Scotland set up the Scottish Dementia Clinical Research Network (SDCRN), with funding from the Scottish Government. Their objective is increase the amount of research in dementia in Scotland and to support researchers. This new investment brings a co-ordinated approach to dementia research in Scotland, in a way that has seen significant new developments in conditions such as stroke and diabetes.

The SDCRN holds a '**research interest register**' for people with dementia, their partners and families, where they can register their interest in being available for research. For further information about the research register and how to enrol, contact:
Scottish Dementia Clinical Research Network (NHS)
2nd Floor West Corridor
Murray Royal Hospital
Muirhall Road
Perth PH2 7BH
Tel: 01738 562322
Email: contact-us@sdcrn.org.uk
Web: www.sdcrn.org.uk

Behind the headlines

You will regularly see headlines in the newspapers and on the internet making claims about new promising breakthroughs in the treatment and or prevention of Alzheimer's and other types of dementia. Many of these should be treated cautiously, as they may only involve animal models or very small numbers of people. You could speak to Alzheimer Scotland or local contact at the SDCRN for further clarification.

You should also not try to self-medicate with any drug or vitamin described in the papers or on the internet as being a promising treatment or a "cure". Speak to your doctor (GP or hospital consultant) – taking any medication could do more harm than good and could even be dangerous if combined with other drugs.

You may also become aware of adverts on TV or radio or in the press seeking volunteers for new research studies in dementia. These will usually give a contact number for you to call. You can expect to be asked some questions about your health and any medication that you are taking. From this, you may be invited to attend for a screening visit to further assess your suitability for the study. You should bear in mind the information contained in this information sheet when making your decision. Some of these clinics are not within the NHS; they are, however, subject to all the same laws and regulations.

Finally.....

There are many laws and regulations governing clinical trials, too many to mention here. However, the primary objective of these laws is to safeguard the public's safety and wellbeing.

All clinical trials conducted in the UK involving new medicines or treatments, or involving existing medicines being used for a new purpose are covered by legislation. Anyone carrying out clinical research is subject to audit and statutory inspection by government's regulatory authorities, to ensure that there are no breaches of these laws. In 2004, these laws became enshrined in the UK statute books.

It takes many years of research to get a new medicine/treatment to the general population and clinical trials and those who kindly agree to volunteer play a vital part of this process.

All decisions about whether or not a drug or treatment can be prescribed are made by the government's licensing authority the MHRA, on

the strength of evidence from clinical trials. All drugs and treatments routinely prescribed today will have undergone these rigorous trials.



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Action on Dementia

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