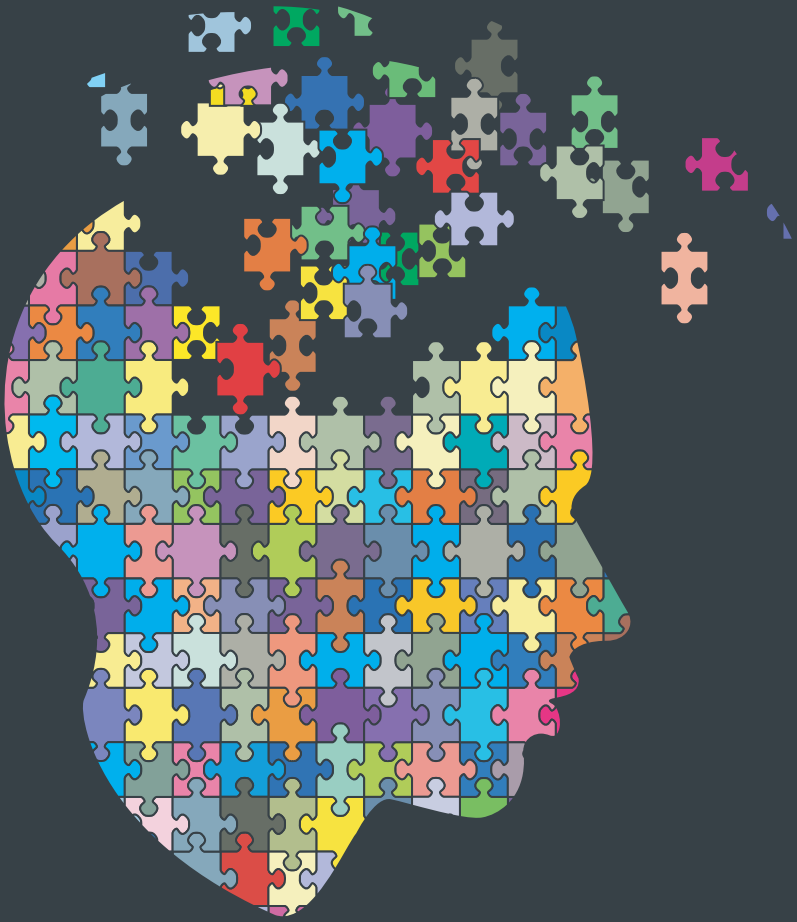
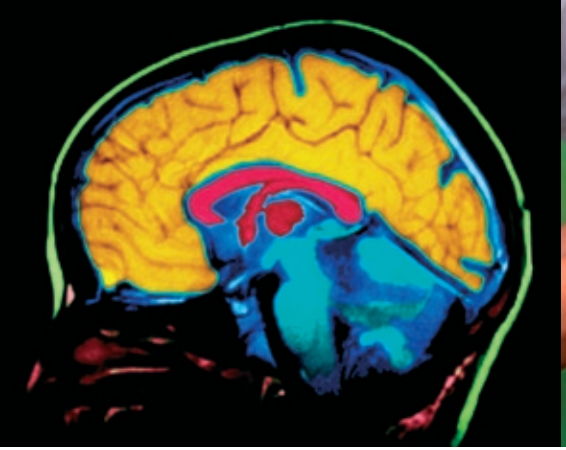


Clinical trials and stroke

Information from The Stroke Association and NIHR Stroke Research Network



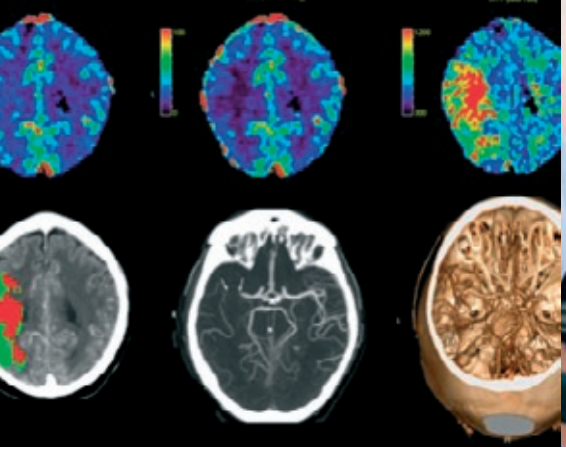
Questions answered

Introduction

Following a stroke, most stroke survivors will have received treatment in hospital. This assists their recovery and rehabilitation afterwards. For example, this could consist of taking certain medications for thinning the blood, having surgery to remove clots or being taught how to walk again by physiotherapists.

In order for treatments to be used on people, they have to be thoroughly researched, tested and evaluated on willing participants in studies called clinical trials.

The information in this booklet has been designed to answer the most common questions about participating in clinical trials, increase your understanding of why they are so vital to stroke survivors and inform you of how to take part.



What are clinical trials?

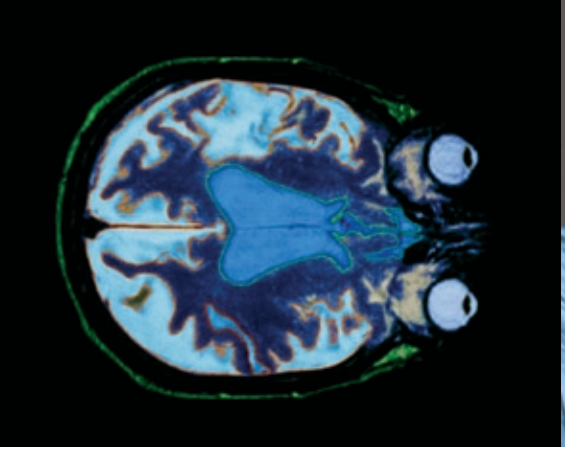
A clinical trial is a health-related research study involving volunteers who are usually patients with a specific disease.

The aims of these trials are to test whether potential new treatments are effective and safe.

How can they help stroke survivors?

Clinical trials can help stroke survivors in the following ways.
They can:

- involve researching ways to prevent stroke and therefore reducing the number of people who have a stroke
- involve treating stroke survivors with the most up-to-date methods
- improve the quality of life for stroke survivors.



What are the benefits and risks of a clinical trial?

Trials are designed very carefully to minimise any risks. However, the risks can never completely be eliminated especially if very little is known about a certain treatment.

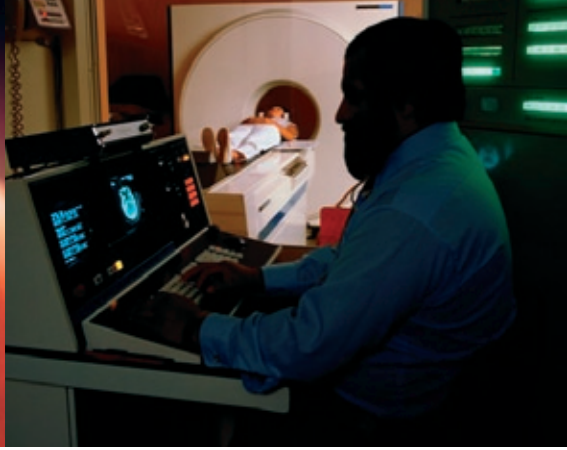
Benefits

Many stroke survivors who take part in clinical trials say they feel a certain satisfaction that they are helping future stroke survivors to have better treatment and therefore have better future outcomes.

There is also the benefit of taking an active part in your own health care and gaining access to new research treatments before they are widely available.

Risks

All trials are different and the most important thing is that you are told by whoever is organising the study what the potential risks and side effects are.



What are inclusion and exclusion criteria, randomised controlled trials and placebos?

Not everyone can take part in a clinical trial. You can be excluded for a number of reasons such as age, gender, type of stroke and other symptoms and therefore you will need to meet a set of conditions. This is also known as **inclusion** and **exclusion** criteria.

It is important to know that not all stroke survivors will receive a new treatment when they take part in a trial. Sometimes, trials need to compare a new treatment with an existing one and participants are randomly allocated to either treatment. This is called a **randomised controlled trial**.

Placebos are commonly used to eliminate any bias of results. A placebo is an inactive drug which has no treatment value and is given to a group of participants to compare another active drug's effectiveness. When taking part in a trial, you need to take into account that you may not receive the active drug, but the placebo instead.

Know Your Blood Pressure

Photograph © South East Coast Ambulance Service NHS Trust

What are the different types of trials specific to stroke?

There can be a huge range of trials ranging from a simple questionnaire which takes minutes to complete to a large clinical study which may take place over a number of weeks, maybe months or even years.

Some past stroke clinical trials have looked at:

- the risk factors which can cause a stroke eg smoking, high blood pressure and high cholesterol
- formulating a universal test (the **FAST** test) to recognise people who have had a stroke to enable them to get to hospital as soon as possible
- the use of clot-busting drugs (**thrombolysis**) to minimise the damage caused by stroke
- improving mobility after stroke using Functional Electrical Stimulation (FES) to improve hand function and grip.

"I am really glad to be involved with SRN. As well as giving me the opportunity to keep up-to-date with developments in stroke research, I feel that our experiences are not only valued, but also that I can use them to make a real contribution to developing future services." Mary, lay member

What is consent?

A researcher cannot enter you into a clinical trial without your agreement or **consent**. For you to give this consent, the researchers must explain the aims, treatment, protocol, possible risks and benefits so that you are fully informed of what you are agreeing to.

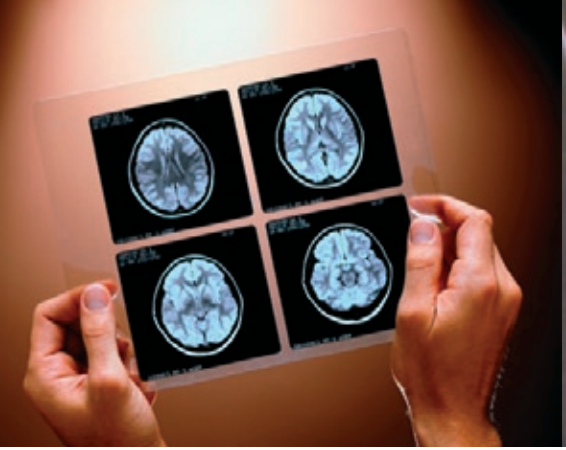
It is your right to withdraw from a trial at any point for any reason even if you have consented initially. You are under no obligation to continue.

Will my information be kept confidential?

All information will be kept confidential unless you give permission for it to be shared. Most research is published at some point and your results may be incorporated but they will always be anonymous. Sometimes even the researchers won't have access to the individual results.

Will I be paid?

This depends on what phase the clinical trial needs participants for. Some will reimburse for travel expenses but it is always best to check with the trial organisers.



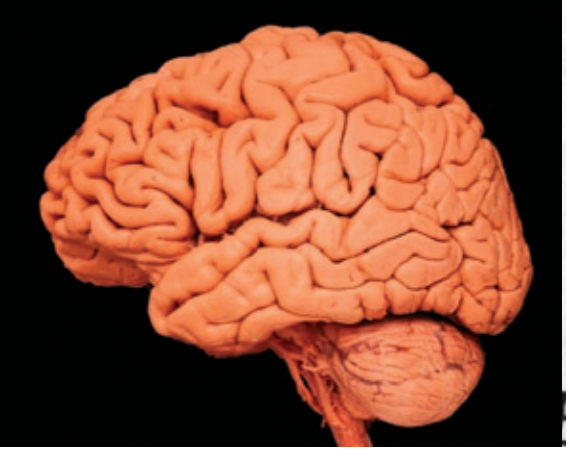
Who is involved in setting up a clinical trial?

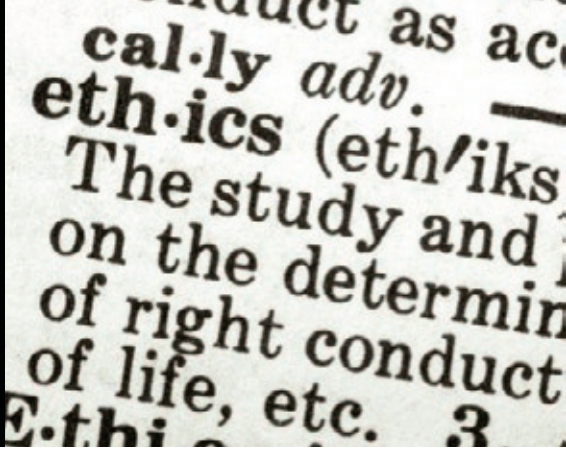
Many people are involved in designing and organising clinical trials. These can include doctors, allied health professionals such as nurses, physiotherapists, occupational therapists and speech and language therapists.

Each trial needs to follow a strict **protocol** (or plan) which has been approved by an ethics committee and NHS research governance working groups.

Research governance

Before any clinical trials are carried out, the research will have been reviewed by experts in that relevant field. They are known as a research governance working group within the NHS and are able to offer independent advice on the quality of the proposed research.





Ethical approval

All trials need to be assessed by an independent Research Ethics Committee (REC) to ensure that participants are protected. A research ethics committee safeguard the rights, safety, dignity and well-being of people participating in research. They review applications for trials and give an opinion about the proposed participant involvement and whether the research is ethical.

RECs are entirely independent of research **sponsors** (that is, the organisations funding and hosting the research) and investigators. This enables them to be completely unbiased in their judgement.

All researchers and their teams who will be carrying out the trials will have been trained to a high standard. They will have gone through regular accreditation so they know exactly what's needed and allowed.

"I never thought I'd get involved in anything to do with research, but research is the key to eliminating the impact of stroke on people's lives. Only through research and involving people like us will critical issues about prevention, treatment and rehabilitation be answered and fully understood." Judith, lay member

What are the different phases of a clinical trial?

Clinical trials are carried out in phases. Each phase has a different purpose and helps the researchers answer different questions regarding safety, dosage and side effects.

Phase 1

This is the first stage of testing a treatment in a small group of people (20-80)

Phase 2

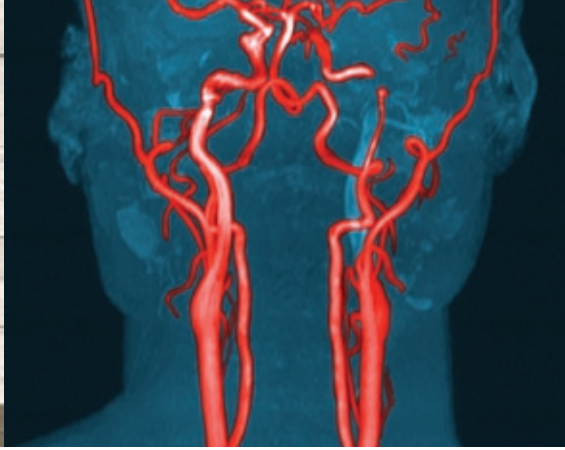
The treatment is given to a larger group of people (100-300) to evaluate its safety

Phase 3

It's now given to even larger groups of people (1,000 -3,000) to monitor side effects, safety and to collect more information

Phase 4

The safety of the treatment continues to be monitored after it has got to market and approved for sale



How do I join?

- Visit the NHS Choices website at **www.nhs.uk**
- Hospital stroke units or stroke club noticeboards have information on local clinical trials
- Contact your local GP
- Visit the NIHR-SRN website at **www.uksrn.ac.uk**

How can I find out more about clinical trials?

You can find out more about clinical trials from the following resources:

Clinical trials: what they are and what they're not
Understanding Clinical Trials
Two information booklets available as PDFs from the UK Clinical Research Collaboration (UKCRC) at
www.ukcrc.org/publications/informationbooklets/

The Stroke Association

The Stroke Association is the only UK wide charity solely concerned with combating stroke in people of all ages.

Every year, an estimated 150,000 people in the UK have a stroke, and almost a million people in the UK live with the effects of a stroke. The Stroke Association funds research examining ways to prevent stroke, research and develop better treatment and rehabilitation for people affected by stroke, and research into understanding changes in the brain after a stroke.

We offer a number of opportunities for people affected by stroke to become involved in our research activities, by helping to choose the research we fund, or by giving us opinions about issues in stroke that they would like to see research funded. If you would like further details of the research we support, please go to www.stroke.org.uk/research. If you would like to tell us your experiences of participating in a research project, you can contact us by email at research@stroke.org.uk or our telephone number is 020 7566 0345.

We rely entirely on public donations to enable us to fund research. We currently award around £2.5m in research each year, but there is much more we could do if we had the money. You can help us to support more life-saving research by making a donation at www.stroke.org.uk

The NIHR Stroke Clinical Research Network, supporting research to make patients, and the NHS, better.

The NIHR Stroke Research Network

The NIHR Stroke Research Network (NIHR SRN) was established in June 2005 as one of the six topic specific networks of the National Institute for Clinical Research (NIHR) Clinical Research Network (CRN). We are funded by the Department of Health and our purpose is to provide the health service infrastructure to facilitate the conduct of clinical trials and other well designed studies in stroke across the full spectrum of disease treatment and prevention through our local research networks and national co-ordinating centre. NIHR SRN works closely with stroke research network structures in Scotland, Northern Ireland and Wales.

Our objectives are to:

- Develop a world-class health service infrastructure for stroke research
- Support the set-up and running of stroke research studies
- Involve people who have had a stroke, their carers, the public, researchers from academia and industry, and a wide range of professional backgrounds in stroke research
- Develop a portfolio of stroke research studies that covers the whole range of stroke prevention, diagnosis, treatment and care
- Work with professional, industry, academic and funding bodies to enhance the quality and increase the volume of UK stroke research.

We would like to thank all the lay members who contributed in the production of this booklet.

The Stroke Association, Stroke House, 240 City Road, London EC1V 2PR
Stroke Helpline: 0303 3033 100 Tel: 020 7566 0300 Textphone: 18001 0303 3033 100
www.stroke.org.uk

NIHR Stroke Research Network, Bioscience Centre, International Centre for Life, Times Square, Newcastle upon Tyne NE1 4EP www.uksrn.ac.uk