

# FACT SHEET

## Taking Part in Research

**Research is a key aspect of our work at the City of London Migraine Clinic. To undertake research studies, we need your help! Results are only as good as the data and this depends on your participation. Before considering taking part, you should understand what might be involved.**

### The importance of research

Research helps us to:

- Improve headache healthcare now and in the future
- Offer the best, most up-to-date treatment advice
- Enable people feel to better and more in control of their headaches
- Develop new ideas and treatments
- Test that treatments work safely and effectively
- Find new treatments that are better than those already available.

### Different kinds of research

We look at mechanisms of headache, quality of life, ways to help symptoms and to prevent headache. At our centre, research can be as simple as completing a questionnaire or a diary.

Alternatively, you might take part in a clinical research trial, which is a health-related study that follows a strict protocol. This detailed plan is designed to safeguard the health of participants and everyone adheres to it. Clinical trials test new treatments, ways of taking or combining them, or compare existing treatments.

### Where does research come from?

We obtain grants to run independent studies. Other clinical trials may be sponsored by pharmaceutical companies. Our clinic could be one of many centres around the world that are recruiting patients into a study. Clinical trials take several years to set up and it may be some years before any of the drugs under study become widely available, if at all.

### Do clinical trials always involve drugs?

No. Any kind of treatment can be studied. All drugs undergo phase I trials, where they are tested on healthy volunteers without headache. Once safety in healthy volunteers has been established, we start studies on people with headache to test how safe and effective the medications are. These are known as phase II and phase III trials. By this time medications have already been tested by hundreds of people. If the drugs are effective, they usually become licensed and can be prescribed by a doctor. Further studies, known as phase IV post-marketing studies, find additional information about optimal use and patient preference.

### What about dummy pills?

Dummy treatments or placebos are inactive pills, liquids or powders with no treatment value. They look the same as the active treatment being studied so neither participant nor researcher can tell them apart. This stops the results being biased. Receiving a placebo is randomly assigned by chance –like pulling a number out of a hat. These trials are “randomised, double-blinded, placebo-controlled” studies. They are the best and most fair type of clinical trial.

Placebos are important in headache research. They can actually be effective treatments because our brains are very good at acting on the power of suggestion. We need to compare a treatment with a placebo to make sure it really does work.

Don't let placebos put you off finding out about a study. In most clinical trials you are more likely to receive active treatment. Some preventative studies allow you to continue with all your usual treatments and others might involve treating a single attack of migraine. If the medication does not work you can usually use your own medications two hours later.

**the City of London Migraine Clinic**

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Website: [www.migraineclinic.org.uk](http://www.migraineclinic.org.uk)

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### What are the benefits?

Benefits are not guaranteed, but:

- By working closely with us, you may have more access to our medical team
- You play an active role in your own care. Some employers recognise this and may support you by giving you time for study visits
- You can gain access to new treatments before they are widely available.
- You may get a free health "MOT"
- You help yourself and others.

### What are the risks?

Some research does not involve much risk, but all will take up varying amounts of your time and attention. Completing a simple questionnaire takes less time than monthly visits over six months, which can take an hour each. Drug trials may have a risk of side effects from the medication. There is a risk is that any treatment offered is not effective, which can be disappointing.

### What about side-effects?

These vary between trials and will be explained carefully to you. With drugs available on the market already, we know the likely side effects. We only test new drugs which earlier testing has shown to be relatively safe. However, we cannot predict all side effects or the effect they might have on you as an individual or your headache.

### How do we ensure it is safe?

The research industry is highly regulated at every stage. There are various national and international legal requirements and quality standards. All clinical studies involving medicinal products must be run according to the guidelines of Good Clinical Practice and Good Manufacturing Practice for the drugs themselves. The study must follow the Declaration of Helsinki, which protects the participants.

Independent scientific review and approval from regional and local ethics committee are also required. This assures that the trial is

scientifically sound, ethical, participants' rights are protected, risks are low as possible, the study is worth any benefits, and has not been done before.

### Are you eligible?

Please volunteer and we will assess if you meet the inclusion and exclusion criteria in the study protocol. We ask you to keep headache diaries, which we check along with past and current medications. You may be excluded if you have serious illness, you are pregnant, planning to conceive or if you are already taking part in another study.

### Giving your informed consent

This means freely agreeing to participate and understanding what is involved. A detailed participant information sheet will explain the trial. Take as much time as you need to decide whether or not to take part. You can ask questions and should discuss it with your family and friends. The study doctor will explain all the risks and benefits before you both sign the informed consent form. You are given a copy to keep. This is not a contract and you can change your mind at any time during the study.

### What happens during a study?

We provide full instructions about taking the study medications, completing diaries and questionnaires. We ask you to record headaches, side-effects, other illnesses and medications. Don't worry about making mistakes; just do the best you can. It is important that you record what happens. All the data is valuable even if the study medication does not work for you, or if you have to withdraw. We watch you carefully with:

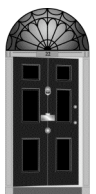
- Trial visits – every 2-8 weeks according to the protocol. Some trials are only one or two visits; others can be 6 or 7. We can usually work around holidays.
- Telephone calls
- Tests – ECGs (heart tracings), blood pressure, pulse, temperature, height and weight

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- Taking samples - blood tests (not all studies), urine or saliva

### What data is collected?

We ask you to keep diary of headache, illnesses and medications. You have to think about your headaches in a more detailed way. When did it start, what time did you use study medication and how bad was the pain at half, 1, 2, 4, 12, 24 and 48 hour time slots.

### What other medication can I take?

If there are restrictions they vary between the trials and we will explain these carefully.

### What happens at the end of a study?

Although you may have finished taking part, it may take some months before everyone completes the study and the results are analysed. We will tell you what medication you took, but there may be a considerable delay until this information is released. You do not get individual results. Overall results will be made public via conferences, scientific journals, migraine charity newsletters and websites.

### Is my privacy protected?

Yes. We work under the Data Protection Act and no one is told about your participation without your permission. With drug trials we request permission to inform your GP to ensure that any other medications/ conditions do not conflict with the protocol. We ask your permission for trial sponsors or their representatives to see your record for the purposes of the trial only. Your name is never used in any reports or results.

### Do I have to pay to take part?

No. The clinical trial visits and any treatments are free of charge. You are not asked to make a donation to the Clinic when you come to see us to take part in a study. We cannot pay you, but we can pay for reasonable travel expenses.

### Do I have to take part?

No. As an active research centre we ask if you mind being contacted about research. You may

opt out if you wish. Your clinic doctor may tell you about a project or you may receive a letter or email and a telephone call. Alternatively you may see advertisements in reception, in our newsletter, on our website or those of Migraine Action and Migraine Trust. There is never any obligation to take part and you can always change your mind for any reason, at any time. Whether or not you take part in our projects does not affect our ongoing care for you.

### Still interested...

Taking part in research is a commitment but can be exciting – it gives you the opportunity to help us, and everyone suffering from headache, to gain knowledge and improve care. Please don't hesitate to give us a call and find out what research we're currently doing, without obligation. Taking part in research will not affect your routine clinical care – and may even enhance it.

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