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# What is a clinical trial?

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We need clinical trials to understand how new treatments work on people. If successful, they may eventually be used in the real world by those who need them for a better quality of life. Find out all about how clinical trials work, along with personal insights from Alice – who has participated in around 50 trials over his life.

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## **Clinical trials for medical advances**

From household painkillers to cancer cures, all medical treatments are tested in clinical trials before they can be used in the real world. After thorough testing in the lab, clinical trials recruit people to try out treatments and study their effects. It's a crucial stage in every new medical advance - and one that's handled carefully to protect the health of those who take part as much as possible.

### Alice's story - 30 years a trial participant

Graphic and web designer Alice is somewhat of a clinical trial expert – his experience as a participant spans 30 years. During this time, Alice has used big cash injections from trials to supplement his DJing career and has used his time on trial wards to work on various projects – from learning web design to helping design outfits for the Spice Girls.

"I've taken part in between 40 and 50 clinical trials. Since I was around 20 years old until five years ago, I was joining clinical trials at least twice a year - and three is the maximum you can do annually.

"Money was the motivation! As it is for a lot of people. There are other **reasons for joining a clinical trial** - it can also be very interesting to glimpse what treatments researchers are developing - but for me, mainly it was good, easy money. Trials also give you time to do things that you otherwise couldn't. I took my computer into one trial and said to myself, in six weeks' time I will know how to build a website, and that's what I did."

## How do clinical trials work?

There are **four different phases of clinical trials** which test the safety and effectiveness of a new treatment in different ways. The types of things a clinical trial might look at includes:

- Testing new treatment drugs for a disease or condition including new doses of drugs or new ways of administering them.
- Testing new diagnosis methods scans, tests, or procedures.
- Finding ways to prevent diseases and conditions developing including vaccines, medicines, or lifestyle changes.
- Examining causes and risk factors for a disease or condition including how lifestyle and genetics influence an individual's risk.
- Exploring ways to improve the quality of life of people with a long-term illness.

Your eligibility for a clinical trial will depend on what it's testing. Some are looking for people with a good health record, while others seek those who have the particular condition or disease that will be studied - for example, clinical trials for asthma sufferers. Factors like your age, gender, and family medical history will also come into play.

### Alice says

"I've been involved in so many different trials, including treatments for HIV before **PrEP** was developed and a trial to extract the painkilling qualities from **cannabis**, but most drug names are long and hard to remember.

"The most memorable ones involved more intrusive administrations of treatment. For example, in one trial I took a medicine as a pill, injection, and through a tube that was inserted through the nose into the stomach. For treatments like the latter, extra money is usually offered. I've also had some side effects - but nothing that lasted more than a few days, and it meant getting discharged early while getting paid for the full trial."

## Who conducts clinical trials?

Clinical trials are research studies led by medical professionals. Usually, the principal investigator is a doctor, and they will have a research team made up of other doctors, nurses, and other healthcare experts. These studies are often funded by academic and national medical organisations, or by private pharmaceutical companies and voluntary groups.

## Where are clinical trials held?

All kinds of buildings can host clinical trials, and typically you will be staying in a hospital-style ward. For your own safety, you won't be able to leave the vicinity until it is considered safe to do so, but it's uncommon to be in total isolation - you'll be with other participants, and forms of entertainment are offered or can be brought in.

### Alice says

"It could be a great experience and I usually enjoyed the isolation of it. The ward beds had curtains to pull around if ever you wanted more privacy. You would hope you're going to have a bed next to someone friendly – and making friends with the nurses was also common. In most clinical trials, you could even have visitors.

"You generally couldn't exercise, as this tends to affect trial results. Some people like me sat on their beds for the majority, but there were also game rooms with things like video games, pool, and snooker.

"Even before laptops, I'd bring in my desktop, monitor, scanner, VCR, portable TV, PlayStation...people would joke about how much stuff I brought with me, but they would all eventually be sharing it for the fun. Because I was so prepared, I loved it."

### Patient picks for Health research

### How do the clinical trial phases work?

#### What is a clinical trial?

If you're volunteering for a clinical trial, it's important to know what 'trial phase' you'll take part in. Clinical trial phases investigate different aspects of a treatment, work in different ways, and come with their own set of benefits and safety considerations.

by Amberley Davis



### **Clinical research FAQ**

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by Lawrence Higgins

## How long do clinical trials last?

This varies significantly, ranging from one day to weeks and even months. It's worth noting that, if a clinical trial does last months, it's likely you'll visit and be discharged from the research site in intervals, rather than spend that whole period on the ward. Each clinical trial will be upfront about exactly how long it will last, and you can opt for shorter ones if you prefer. For Alice, the longer stays held the most appeal.

### **Alice says**

"The shortest I've participated in was one day, and the longest were in six-week solid blocks. I prefer the latter because I enjoy the time they give you for learning and other tasks - and they also pay well."

## Clinical trials - no Frankenstein's lab

The idea of taking part in a clinical trial may feel scary for some people, but consenting to taking part doesn't mean relinquishing all control to the researchers. In the UK, regulations go to great lengths **to make trials safe**. This includes:

- Ethics committees that review each trial to look after your "rights, safety, dignity and wellbeing" as a participant<sup>1</sup>.
- An informed consent process to provide you with all the information you need so that you fully understand the risks and potential benefits of taking part.
- The right to withdraw at any time signing a consenting document isn't a legal contract, and you can change your mind at any time.

## Alice says

"I have a very positive outlook on clinical trials. When people find out I take part, some reactions can be negative, because they have this idea that you're essentially a guinea pig - or they imagine Frankenstein's lab! But it's not the case that they can do anything with you they wish, and in my experience, I find it to be highly regulated."

To reduce his risk of injury, Alice had his own criteria for which clinical trials he'd be happy to join.

"For example, I've always asked the researchers how many people a drug has been tested on before. There are many rounds of clinical trials, so if you prefer to not be one of the very first people trialling treatment, you can find one where it has already safely passed previous phases involving people. Although, if you are among the first tested, the dose is usually very small."

He adds that, while there are health considerations, there are also health positives.

"You get amazing health screenings which give you a very informed picture of your health - and you can act on the information you find. From blood tests, I found out that I had a low platelet count - a condition called **thrombocytopenia** which can increase your risk of problems such as bruising and excessive bleeding."

## How to take part in clinical trials

It's usually a matter of searching online for current clinical trials. Most researcher websites will provide lots of information and application forms, as well as contact details if you have any more questions.

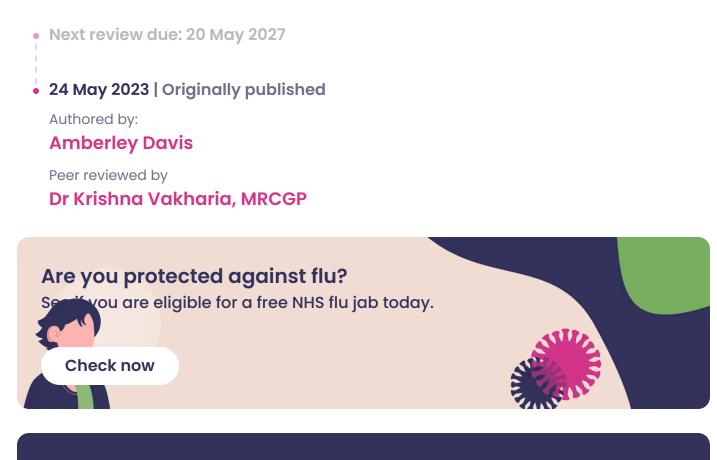
For Alice and others who join multiple studies, word of mouth from other people they meet on trials can also give top insights - this could be anything from how much a trial pays or it's perceived shortcomings, to handy details like it having a five-star chef serving delicious food.

## **Further reading**

1. NHS Health Research Authority: Research ethics service and research ethics committees.

## **Article history**

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