

# Taking part in research

A guide for teenagers and young adults (aged 13-25) with cancer who are considering taking part in a research study or clinical trial



**Why should I take part?**

Young people with cancer do not always have the same opportunities as children and older adults to take part in research<sup>1</sup>. There is some evidence that taking part in clinical research may improve a patient's outcome<sup>2</sup>.

We know that having a cancer diagnosis is an emotionally hard and overwhelming time. You may have been approached by your hospital team to ask if you would like to take part in a research study or clinical trial.

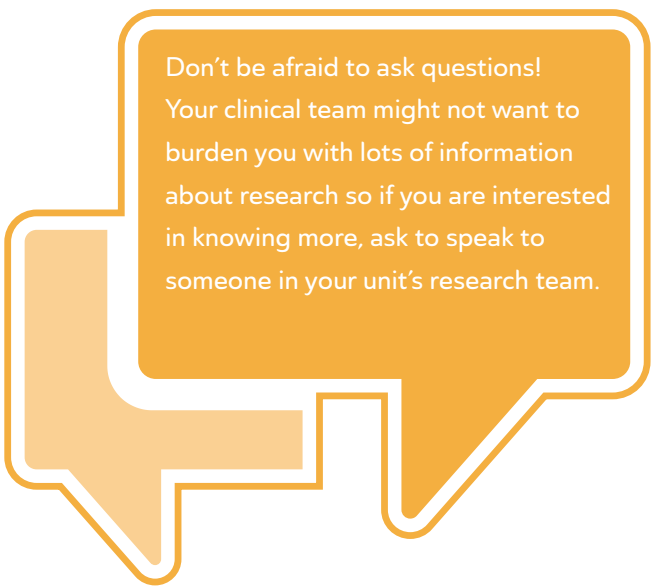
To be able to make the right decision about what will happen if you take part, we have put together some facts about clinical research. This is in response to suggestions from other young people who have been through or are still going through treatment for cancer.

This factsheet explains the different types of clinical research that you may be invited to take part in. This will depend on whether there is a research study available in your hospital that you are eligible for. You can check this by either asking your clinical team or looking on the UK Clinical Research Network database (<http://public.ukcrn.org.uk/search/>).



**Why am I being told about clinical research?**

The research team on your unit and your doctor will also be happy to answer your questions about the availability of research and how to find out more.



Don't be afraid to ask questions!  
Your clinical team might not want to burden you with lots of information about research so if you are interested in knowing more, ask to speak to someone in your unit's research team.

## What is research?

“Research is a process of steps used to collect and analyse information to increase our understanding of a topic or issue. It consists of three steps: pose a question, collect data to answer the question, and present an answer to the question.”<sup>3</sup>



## Why is clinical research important?

**Doctors and scientists are constantly working to find new cancer treatments and improve the ones that already exist.** Outstanding progress has been made in cancer treatment in children and young people over the last 40 years but there are still many things we don't know about. For example, the best way of treating all types of cancer or the best way of supporting you after treatment has ended.

Research allows us to do this by testing new treatments, finding out about your experiences or developing other systems that will help make having a cancer diagnosis more bearable.



## Who organises clinical research in the NHS?

Clinical research might be developed by your hospital team, scientists in universities or by pharmaceutical companies. It will need approval from an NHS Research Ethics committee and the Health Research Authority to ensure the study is safe and ethical.

Your research team can include nurses, pharmacists, clinical trial practitioners and data managers who work across a huge variety of research projects. They will be happy to talk with you about any research studies that you may be able to participate in<sup>4</sup>.

## What are the different types of clinical research?

**There are several different types of clinical research:**

- clinical trials to improve the way we give the current standard treatment for different types of cancer
- looking more closely at the biology of cancer and its treatment
- looking at the way in which drugs are used by the body
- improving the quality of life and understanding more about long-term effects
- improving services
- looking at new drugs (early phase clinical trials)
- understanding symptoms and how to manage these more effectively

## What are clinical trials?

A clinical trial is a research study to find the most effective treatment for a particular disease. Before a new treatment is available to all patients, it must be tested to be sure it is safe and effective. This is done through clinical trials.



## Can everyone take part?



**Not everyone can take part in a clinical trial.** Each trial will have specific rules about who can take part such as type of cancer and age. These will always be discussed with you.

## How does it work?

**Once you or your parents have given consent, your doctor or research nurse will register you on the trial.** If a trial is randomised, a computer will assign you the treatment you will be given – either the new treatment or the best treatment which is currently available. This makes sure that there is an even split of patients across the trial so that an accurate comparison can be made. It also means that each patient has a fair and equal chance of being allocated either treatment.

## What are the different types of trial?

There are three different kinds of trials (known as 'phases') and each phase finds out something different about any new treatment.

**Phase I** trials test new treatments which have not been tested before in children and young adults with cancer. They help us to find the correct doses of new drugs and any possible side effects. These trials only happen in a small number of patients, usually in patients who have had all available standard treatment.

**Phase II** trials try to find out if the new treatment is effective at the dose(s) chosen in Phase I. They aim to find out how well the new treatment works for particular types of cancer and to highlight any side effects.

**Phase III** trials compare the new treatment to the best existing treatment. These involve a larger number of patients who receive either the new treatment or the current standard treatment to see which one works better. The key question asked is: 'Is this new treatment better than what is currently being used?'

Some clinical trials can also focus on improving other aspects of your care such as trials of drugs to help you stop being sick, complementary therapies or ways of supporting you emotionally.

## What happens during the trial?

**If you agree to take part in a trial, your medical notes, tests and scans will be reviewed by your medical team to ensure you are eligible.**

Once you have signed a consent form, you will be registered onto the trial and allocated to a treatment plan. You will be asked to attend all of your scheduled clinic appointments, but you will also meet your research team who will need to know the following information:

- any medication you are taking, including prescribed medication, over the counter medication and herbal medications/remedies;
- any symptoms, side effects or complaints you are currently experiencing;
- any hospital admissions whilst you are on trial treatment.

Other things you may be asked to do include:

- **Completing questionnaires**

These are important because they will tell us more about how the treatment is making you feel and how it is affecting other parts of your life.

- **Providing extra samples of blood or urine**

Where possible, these will be taken at the same time that you have your routine procedures and blood tests. If additional procedures or visits to hospital are needed, this will always be explained

to you before you decide whether to take part in a trial.

It is important that this is not the main reason for deciding whether or not to take part. You can discuss with your research team a way in which treatments can be combined or if there is any financial/transport support to help you attend these visits.

Taking part in a trial may last until the treatment ends, but often the trial will also include a follow-up period, so the research team will continue to record information relating to you and your treatment. This will usually be at routine clinic appointments but sometimes you may be asked to visit the hospital specifically to provide this information. This will be explained to you before you agree to take part. Again, do not let this put you off taking part in a trial, your research team will be able to talk through possible options to make sure this is not a burden to you.

You will meet your research team regularly during your time on trial. The results of your tests will be held in your medical notes as well as information about your treatment and any side effects you experience. This information will be inputted into the trials database by the research team. Data about you will always be anonymised when it is submitted to the trials database unless you are told otherwise.

## What happens at the end of the trial?

**All of the results from every patient who participated in the trial will be analysed.** This information will show whether or not the new treatment is better. If it is, it will be approved for general use and will become the new standard treatment for future patients.



## Is it safe?

The safety of patients involved is paramount and there are laws that govern how clinical trials are conducted. Any unexpected side effects in patients while they are on a trial are promptly reported and it is very rare that a trial is discontinued. If new information about your treatment or condition becomes available whilst you are on a clinical trial, this will always be discussed with you. **Your safety is your research and clinical team's priority.**

It is very important that you tell your research team about any problems you experience whilst you are on a trial so that they can help to resolve these as quickly as possible, and inform the central trials office when necessary.

## What happens in other types of clinical research?

You may be offered the opportunity to take part in other types of clinical research. Some of these are large national studies and some are smaller ones taking place in only one or two hospitals. According to the NHS Constitution<sup>5</sup>, you should be informed about all research you are eligible for in your unit but you do not have to take part in everything if you do not wish to.

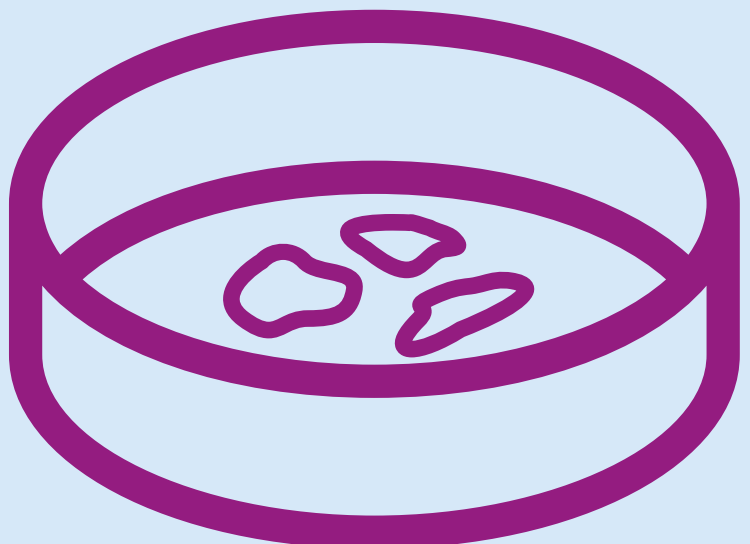
The study may involve taking a piece of tumour from a routine biopsy, completing questionnaires or taking part in interviews.

As with clinical trials, you will have contact with the research team during the study period and when it has ended the results will be analysed. Often the results from other types of clinical research are used for more varied reasons. For example:

- by understanding the biology of your cancer, scientists can develop new types of drugs to try and treat them (the work done before phase I trials);
- understanding your experience or views on treatment or living with cancer can help us develop services.

Other types of clinical research are as important as clinical trials in discovering new treatments and learning new information about cancer.

Not every hospital conducts every research study, so if you find out about a research study you want to take part in, but it's in a different hospital, please contact the research team directly or ask your clinical team to do this on your behalf. You might have to change your hospital and clinical team, but they will support you to make the decision you think is best for you.



## Who decides if you can take part in research?

The simple answer is **YOU!**



You will get all the information you need, in a way that you can understand, so you can make an informed decision about whether or not to take part in a trial or research study.

If you are under 16 years old, you are not old enough to legally give your consent so the responsibility will fall to your parents, but both you and your parents will be given an information sheet describing everything that will happen in the study.

Either you or your parents will then sign the consent form to agree to take part in the study.

**It's really important that you and your parents understand everything that may be involved by discussing this with your doctor.**

## How can you decide to take part?

Ask lots of questions to find exactly what may be involved! To help you decide, the researcher should answer any questions you might have such as:

**What is the study trying to find out?**

**What will I need to do?**

**What type of treatment will I receive?**

**Will I need extra tests?**

**Will I need to come to hospital more often?**

**Will I have to travel to another hospital somewhere else in the country?**

However, there are some overall benefits and risks which apply to all clinical trials and research studies.

## What are the benefits of taking part in research?

- you may receive a new therapy that is only available on a trial or study
- the new therapy may be more effective than the standard treatment
- the emphasis is on safety so you will be monitored closely
- you will be contributing to a study which may help others in the future
- you may get to talk to someone independent about how you feel
- you may get to meet other young people in the same situation as you



## Are there any risks?

It is important to understand that clinical research sometimes can involve risks.

- you may have to make more hospital visits and undergo more tests
- the new treatment may have unexpected side effects, but this is unlikely on a Phase III trial and you will always be closely monitored.

You may want to talk to your parents, partner or a best friend, but sometimes you might want to talk to another young person who is receiving the same treatment. If you speak to your research team they will be able to find out if there is another young person available to talk to you.

Don't worry – you can change your mind at any point! If you don't want to take part any more, just let your research or clinical team know. Stopping will not affect the way in which your clinical team acts towards you and you will still receive the best available treatment.



## How do you find out about the results?



**There is no standard way for patients to be kept updated about the research they have taken part in.** We outline three ways you can find out about results:

1. Many clinical research studies have their own websites to keep patients and healthcare professionals updated about the study, for example [www.brightlightstudy.com](http://www.brightlightstudy.com), [www.euroewing.eu](http://www.euroewing.eu).
2. Often research teams have newsletters to keep participants updated about their study.
3. Some studies can take many years to finish so you may have forgotten that you have taken part. Most studies will eventually be published in scientific journals. The language of these can often be confusing but you can email the author (their details will be on the paper), who will be able to provide you with a simplified explanation.

## Other sources of information

### Children's Cancer and Leukaemia Group

[www.cclg.org.uk](http://www.cclg.org.uk)

### Macmillan Cancer Support

[be.macmillan.org.uk/be/s-610-clinical-trials.aspx](http://be.macmillan.org.uk/be/s-610-clinical-trials.aspx)

### Nuffield Council on Bioethics

Nuffield Council on Bioethics provides an informative animation about taking part in research: [www.youtube.com/watch?v=6yaKwLG\\_vLE](http://www.youtube.com/watch?v=6yaKwLG_vLE)



## References

- <sup>1</sup> Fern, L.A., Lewandowski, J., Coxon, K.M., Whelan, J.S., 2014. Available, accessible, aware, appropriate and acceptable: a strategy for improving participation of teenagers and young adults in cancer clinical trials. *Lancet Oncol.* 15, e341ee350
- <sup>2</sup> Taylor RM, Solanki A, Aslam N, Whelan JS, Fern LA. (in press) A participatory study of teenagers and young adults views on access and participation in cancer research. *European Journal of Oncology Nursing* doi.org/10.1016/j.ejon.2015.07.007
- <sup>3</sup> Nachman J1, Sather HN, Buckley JD, Gaynon PS, Steinherz PG, Tubergen DG, Lampkin BC, Hammond GD. (1993) Young adults 16-21 years of age at diagnosis entered on Childrens Cancer Group acute lymphoblastic leukemia and acute myeloblastic leukemia protocols. Results of treatment. *Cancer* 15;71(10 Suppl):3377-85.
- <sup>4</sup> Creswell, J. W. (2008). *Educational Research: Planning, conducting, and evaluating quantitative and qualitative research* (3rd ed.). Upper Saddle River: Pearson
- <sup>5</sup> These are just some examples of non-research nurse job titles but there are many others used. These refer to people with science or other healthcare background who have been trained over a number of years to conduct research with patients. All healthcare professionals undertaking research in the NHS will have their 'Good Clinical Practice' certificate, which is the training needed to conduct clinical research in the NHS.
- <sup>6</sup> <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>



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 ChildrensCLG   CCLG\_UK

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Reviewed by Sarah McKay, Research Sister TYA Cancer Service, University Hospital Southampton and Diane Hubber, TYA Clinical Nurse Specialist, Leeds Teaching Hospitals Trust, on behalf of the CCLG Information Advisory Group, comprising multiprofessional experts in the field of children's cancer and parents and survivors.

### Children's Cancer and Leukaemia Group (CCLG) is a leading national charity and expert voice for all childhood cancers.

Each week in the UK and Ireland, more than 30 children are diagnosed with cancer. Our network of dedicated professional members work together in treatment, care and research to help shape a future where all children with cancer survive and live happy, healthy and independent lives.

We fund and support innovative world-class research and collaborate, both nationally and internationally, to drive forward improvements in childhood cancer. Our award-winning information resources help lessen the anxiety, stress and loneliness commonly felt by families, giving support throughout the cancer journey.

Our work is funded by donations. If you would like to help, text 'CCLG' to 70085 to donate £3. You may be charged for one text message at your network's standard or charity rate. CCLG (registered charity numbers 1182637 and SC049948) will receive 100% of your donation.

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