



STRONG-AYA: Implementing a Core Outcome Set (COS) for Adolescents and Young Adults (AYA) with Cancer

This is a multinational, multicenter European project, led by the STRONG-AYA consortium. We are collecting data related to the health and wellbeing of adolescents and young adults with cancer to help shape services in the future.

We would like to invite you to take part in a research study. Should you decide to take part, it is important for you to understand what the research is about, why the research is being done, and what it will involve for you. So please read this information sheet carefully. If you wish, you might find it helpful to speak to others about this study, such as members of your hospital team, family, or friends.

**Please ask us if there is anything that is not clear
or if you would like more information!**

What is the purpose of the study?

A growing number of young people in the UK are surviving cancer. Receiving a cancer diagnosis and undergoing treatment as a young person can have a big impact on a young person's life, how they feel and think about their future. We know a lot about the medical support needed by young people with cancer, but we also need to understand how to provide care for other aspects of life that may be affected by the diagnosis.

STRONG-AYA is a European project that aims to identify and address the distinct, age-specific needs of Adolescents and Young Adults (AYAs - defined as people aged 15-39) diagnosed with cancer. To do so we will put into routine cancer care a Core Outcome Set (COS) which is a set of the most important outcomes that should be measured during routine care and when researching a particular health condition. The STRONG-AYA COS is made up of two parts: a set of questions related to your overall health and wellbeing, lifestyle, quality of life, sleep, daily activities, and impact on mental health. The second is a series of clinical questions that will be recorded by your clinical team on aspects of your cancer such as the type and stage of your cancer and your medical progress.

In the UK, the study aims to implement this COS in everyday care, to see how well it works in practice within two NHS settings: Leeds Teaching Hospitals NHS Trust and The Christie NHS Trust in Manchester.

By better understanding how a diagnosis affects young people, we can then develop a strategy to make sure your needs are identified and addressed, and you are supported in the best way possible.

Why have I been asked to take part?

STRONG-AYA is inviting young people who are currently aged 15-39 and had a cancer diagnosis a minimum of 10 weeks ago (this could be any time in the past as long as you were aged 15-39 at the time of diagnosis) to take part in the study.

Do I have to take part?

Your participation is entirely voluntary. If you decide to take part, but later want to stop, or if you only want to partially answer the survey, you are free to do so. You do not have to give a reason and it will not have any implications for your care or future participation in this or future studies.

What happens if I take part?

Once you have agreed to take part in the study by signing the consent form, we will ask you to complete the COS survey once a year for up to 3 years. This will take approximately 30 minutes each time. We recommend you complete the survey at least once a year for the duration of the study, but you are welcome to complete it more frequently often if you wish. The survey can be completed either at home or in hospital, on paper or online. If you would prefer to complete the survey with one of the research nurses, you can do so either in person or over the phone. Clinical information related to your diagnosis will also be collected by the hospital to complement the survey.

You may be given the opportunity to provide feedback on the COS and discuss in more detail which aspects are most relevant to you. This is optional. Should you consent to the feedback part of the study, we will schedule a date and time for a recorded interview to take place either face-to-face or online (Microsoft Teams or another NHS and University of Leeds approved video-conferencing

software). This interview will be recorded, then transcribed and anonymised by the study team. Some quotes may be included in published materials related to this study, but all quotes will be anonymous. If you would prefer us not to use any of your quotes please let us know.

To stay in touch, we will ask for your preferred contact details, which can be updated at any time by contacting the study team (their contact details are listed at the end of this document). We will use this information to send you reminders when your next survey is due and let you know of the study findings. You also have the option to provide us with contact information of a trusted family member or a close friend who we can speak to in case we are unable to reach you.

What are the possible disadvantages and risks of taking part?

We are asking you to give up some of your time to take part in this study. The survey should take up to 30 minutes to complete. If you also decide to take part in the interview, this will take another 30 minutes.

Whilst we do not think that there is anything to be worried about in taking part, if you experience any difficulty because of taking part in this study, please let the study team know and they will support you. You are free to withdraw at any time, with no effect on any of your treatment or care.

What are the possible benefits of taking part?

Follow-up clinic visits typically focus on scan and test results or side effects. As your answers to the COS survey will be accessible to your clinical team, they may wish to discuss these with you during your follow-up consultations. This can help make the aspects that are most important to you a feature within your consultations. Taking part in the project is an opportunity to be part of the research required to improve the services and support we offer to future patients.

Who has reviewed this study?

This study has been reviewed by people who have the experience of cancer themselves and independent experts in this area of research, from the University of Leeds, Leeds Teaching Hospitals NHS Trust, The Christie NHS Trust, University of Manchester, the European Union, Innovate UK, as well as the STRONG-AYA Consortium teams in Amsterdam, Paris, Milan, Warsaw, Lyon and Southampton.

All research in the NHS is also approved by the Research Ethics Committee, an independent group that works to protect your interests. This study has been reviewed by the University of Leeds as sponsor and given favourable opinion by the Health Research Authority (IRAS ID: 335080).

What happens when the research project stops?

Once you consent you will be involved in this study for up to three years. After finalising your participation in this project, we will not ask you to do anything else. At the end of the project, we will publish the results in medical journals and share our findings through conferences – but you will not be identifiable in any of these activities. These publications and presentations will then be made available on the STRONG-AYA website (<https://strongaya.eu/>) and our research team's website (<https://pcor.org.uk/tya/>).

Please feel free to ask the study team for more information about how you can get involved with future studies involving novel data collection or become part of a patient advisory group that helps us develop these types of studies.

What if there is a problem?

If you have any study-related issues, including problems accessing the online COS survey, you can speak to your clinical team or the research staff who told you about the study. Their contact information can be found at the bottom of this information sheet. We also include the details of another researcher who is independent of the project, who you can contact if you would like a neutral opinion on anything study related. For your reassurance, the survey has been checked by other young cancer patients as well as the wider study team to ensure they do not cause any concern.

If you have any complaints about the way in which this research project is being carried out or a complaint about anything else relating to the project, please try to discuss them with the study team first. For an independent opinion on your complaint please contact The University of Leeds, Sponsor Representative at governance-ethics@leeds.ac.uk.

If these issues are not resolved, please contact the Patient Advice and Liaison Service (PALS) on 0113 206 6261 or email: patientexperience.leedsth@nhs.net.

If you have any worries or concerns about your health, please contact your Key Worker/Clinical Nurse Specialist, any of the members of your clinical care team, or the Macmillan Cancer Support Line on 0808 808 00 00 (7 days a week, 8am-8pm).

Will the information I give be kept confidential?

Yes. It is very important to us to respect your information and keep it confidential. We work within strict governing rules covering data protection and confidentiality. For further information, please see the Privacy notice at the end of this document.

Paper copies of the consent form, contact details, and responses to the COS survey and your clinical information will be stored securely in the University of Leeds research offices at St James's University Hospital, accessible to authorised project staff members only. Your contact details will be stored separately to your responses to the COS survey so that no one can link them back to you.

Once you completed the survey, to protect your identity, the information collected from the COS survey and clinical information will be 'pseudonymised'. This means that your identifiable details will be removed from the data, and you will be allocated a unique participant number to ensure no one outside of your clinical and study team can identify you. Only this 'pseudonymised' data will be available to researchers for the STRONG-AYA analysis.

The optional interview will be digitally-recorded and linked to your unique participant number, the recording will be deleted once transcribed with any identifiable information removed. After you finish your involvement in the study, all electronically generated data (COS and clinical information) will be anonymised and stored in the University of Leeds secure research environment

with limited access to designated members of the study research team for 5 years. The anonymised data will be available for future approved research using specific data sharing templates defining purpose, ethical approvals, security, confidentiality, and funding.

The data collected within the STRONG-AYA project in Leeds will be added to the Yorkshire Specialist Register of Cancer in Children and Young People (MREC 00/3/001, IRAS ID: 222495) for public health and social research. This enables the NHS to better understand the service needs for young people with cancer and the Yorkshire population, to be informed about their long-term health and social outcomes including quality of life. For more information about the Yorkshire Specialist Register including details on their privacy notice, please visit: <https://ysrccyp.org.uk/>.

Who is organising and funding the research?

STRONG-AYA is funded by HORIZON Europe and UK Research & Innovation. STRONG-AYA in England is sponsored by the University of Leeds and is being conducted within Leeds Teaching Hospital NHS Trust and The Christie NHS Trust. The study has been organised and is conducted by the STRONG-AYA Consortium across multiple countries. For more information, please visit: www.strongaya.eu.

**Thank you for reading this and considering participating
Please ask us any questions you may have!**

Contact the Study team for more information:

Study Team – Tel: 0113 206 7500. Email: leedsth-tr.strongayaleeds@nhs.net

Chief Investigator, Prof Dan Stark - Email: d.p.stark@leeds.ac.uk

If you'd like to discuss any study related issues with someone outside the study team, please contact our Senior Research Nurse Gwen Saalmink on Gwendolyn.saalmink@nhs.net.

Privacy notice

Who is responsible for this study?

The University of Leeds is the Sponsor for the study and is legally responsible for making sure your information is used appropriately and securely. The University of Leeds and Leeds Teaching Hospitals NHS Trust collaborate to ensure your data is used appropriately and securely. HORIZON EU and UK Research & Innovation will not have access to any information which could identify you as an individual. They will also not have access to any information from individual patients.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This will include your:

- Name
- Your contact details (telephone numbers, postal and email address)
- Contact name and telephone numbers for a next-of-kin in case we cannot reach you (unless you opt out)
- NHS number
- Date of birth
- Sex
- Marital status
- Employment/educational status
- Ethnicity
- Information from the medical records about your diagnosis, treatment and health including results from scans, blood tests or biopsies.

Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Relevant professionals will use this information to do the research or check your records to make sure the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will be given a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write reports in a way that no one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop taking part in the study at any time, without giving a reason, but we will keep the information about you we already have, including interview data which has been anonymised. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. If you decide that you would like your data removed from the study, please tell us as soon as possible – we will honour your request as long as this is practicable.

We will keep the pseudonymised information we already have about you for 5 years following the end of study. Survey information you offered for day-to-day clinical care will be added to your clinical care records and will only be accessible to your clinical care team.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. For instance, your data will be linked to the Yorkshire Specialist Register for Cancer in Children and Young People. If you wish to opt out of your data being linked to the Yorkshire Specialist Register for Cancer in Children and Young People, please follow the guidance on their opt out process which can be found here: https://ysrccyp.org.uk/wp-content/uploads/sites/103/2021/11/YSRCCYP_Database_opt_out_policy_2020.docx

Data generated within this study may be used in further research or archived and/or shared, once it is pseudonymised so does not contain identifiable sensitive information. The pseudonymised data from this study (which does not include identifiable information) will be available for sharing upon request using specific data sharing templates defining purpose, security, confidentiality, ethical approval and funding. Your pseudonymised data will be kept for 5 years after the study has finished in the University of Leeds locked and secured file cabinets (if in hard copy) or in a password-protected database on the University of Leeds secure server (if in electronic format).

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- NHS Health Research Authority – Information on patient participation in research
[Patient data and research leaflet.pdf](#)
- By contacting the University of Leeds Data Protection Officer at dpo@leeds.ac.uk or visiting <https://dataprotection.leeds.ac.uk>
- University of Leeds Privacy Statement for research participants
<https://shorturl.at/jtP46>
- Information on the Yorkshire Specialist Register of Cancer in Children and Young People
<https://shorturl.at/eAGRW>.