



strong aya

Parent/Guardian Information Sheet

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 your child to take part in a research study. To help them decide if they want 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. 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 and, 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 child's 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 their clinical team on aspects of their diagnosis such as the type and stage of cancer and 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 child's needs are identified and addressed, and they are supported in the best way possible.

Why has my child 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 they were aged 15-39 at the time of diagnosis) to take part in the study.

Does my child have to take part?

Your child's participation is entirely voluntary – if they do not wish to take part, they do not have to. If your child decides to take part, and then later decides to stop, or only partially answer the survey, they are free to do so. They do not have to give a reason and there will be no implication to their care following this.

What happens if my child decides to take part?

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

Your child may be given the opportunity to provide feedback on the survey and discuss in more detail which aspects were most relevant to them. This is optional. Should your child 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. Some quotes may be included in published materials related to this study, all quotes will be anonymous, but if you would prefer us not to use any of your child's quotes please let us know.

To stay in touch, we will ask for your child's 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 reminders when the next survey is due and let you know of the study findings. There is also an option for your child to provide us with contact information of a trusted family member, such as yourself, who we can speak to in case we are unable to reach them.

What are the possible disadvantages and risks of my child taking part?

We are asking your child to give up some of their time to take part in this study. The survey should take up to 30 minutes to complete. If they 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 your child experiences any difficulty because of taking part, please let the study team know and they will offer support. Your child is free to withdraw at any time, with no effect on their 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 the answers to the COS survey will be accessible to your child's clinical team, they may wish to discuss these with you and your child during follow-up consultations. Taking part in this research can help make the aspects that are most important to your child a feature within their consultations and is also an opportunity 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 child's interests. This study has been reviewed by the University of Leeds as sponsor and given favourable opinion by the Health Research Authority (IRAS: 335080).

What happens when the research project stops?

Once you and your child consent to this study, your child will be involved for up to 3 years. After this, we will not ask them 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 your child 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 your child 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 your child is experiencing any study-related issues, including problems accessing the online COS survey, the study team can be contacted, their contact information can be found at the bottom of this information sheet. We also include the details of another independent researcher who is not part of the project, who can be contacted for a neutral opinion on anything study related.

If you or your child have any complaints about anything relating to the project, please discuss them with the study team in the first instance. 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 your child has any worries or concerns about their health, please contact your child’s Key Worker/Clinical Nurse Specialist, any of the members of the clinical care team, or the Macmillan Cancer Support Line on 0808 808 00 00 (7 days a week, 8am-8pm).

Will the information my child offers be kept confidential?

Yes. It is very important to us to respect all personal 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 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 child’s contact details will be stored separately to their responses to the COS survey so that no one can link these.

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

The optional interview will be digitally recorded and linked to the unique participant number, the recording will be deleted once transcribed with any identifiable information removed.

After they finish their 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 or secure server 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 your consideration taking part.
Please ask us any questions you or your child 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 child's information is used appropriately and securely. The University of Leeds and Leeds Teaching Hospital NHS Trust collaborate to ensure the data collected is used appropriately and securely. HORIZON EU and UK Research & Innovation will not have access to any information which could identify your child as an individual. They will also not have access to any information from individual patients.

How will we use information about your child?

We will need to use information from your child's medical records for this research project. This will include their:

- Name
- Contact details (telephone numbers, postal and email address)
- NHS number
- Contact name and telephone numbers for a next-of-kin in case we cannot reach your child (this can be yourself)
- Date of birth
- Sex
- Educational status
- Ethnicity
- Information from the medical records about your child's diagnosis, treatment and health including results from scans, blood tests or biopsies.

Your child's 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 conduct research or check your child's records to make sure the research is being done properly. People who do not need to know your child's individual information will not have access to it. Your child's research data will be given a code number instead. We will keep all information about your child safe and secure. Once we have finished the study, we will keep some of the anonymised data on the University secure server so we can check the results. We will write reports in a way that no one can work out that your child took part in the study.

What are your child's choices about how their information is used?

Your child can stop taking part in the study at any time, without giving a reason, but we will keep the information we already collected, including interview data which has been anonymised. If your child later decides that they would like their data removed from the study, we suggest they inform us as soon as possible – we will honour their request as long as this is practicable.

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

If your child agrees to take part in this study, they will have the option to take part in future research using the data saved from this study. For instance, their data will be linked to the Yorkshire Specialist Register for Cancer in Children and Young People. If you or your child 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 child's 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 child's information is used?

You can find out more about how we use your child's 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>.