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Participant Information Sheet for Young Participants

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

This is a project taking place across Europe to learn more about how cancer affects teens and young adults. We're asking young people with cancer to share how they feel about their health and well-being during and after treatment. We will use this information to improve the support and care provided to you and others diagnosed with cancer.

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's the study about?

We know cancer can be tough, especially when you are young. Whilst doctors have learned a lot about treating the illness itself, we also need to understand more about how it impacts other parts of your life—like school, relationships, home life, and your future plans. That's where you come in! By sharing your experiences, you'll help us figure out better ways to support you and others in similar situations.

Why have I been asked to take part?

You are being invited to take part because we want to hear directly from young people who have been affected by cancer. We know that everyone's experience is different, and your insights will help us get a full picture of what life is like during and after treatment to help improve care provided to people like you.

Do I have to take part?

No, it is totally up to you. If you decide to join but later change your mind, that's okay too—you can stop at any time without it affecting your care or your participation in this or future studies. If you decide to take part but only want to answer some of the questions but not others, that is also fine.

What happens if I take part?

If you choose to take part, we will ask your parent/guardian to complete a consent form and you will fill in a similar, but shorter, assent form.

You will then fill out a survey about your overall well-being, including how you are feeling, what your daily life is like, and any challenges you are facing. The survey takes about 30 minutes each time to complete. You can do it in clinic or at home; online on an app or on paper—whatever works best for you.

We will ask you to complete this survey once a year for up to three years, but you can do it more often if you would like. We recommend you complete it at least once. We will also take some medical information from your records. If you would prefer, someone from our team can help you complete the survey in person, over the phone, or online. You may be given the opportunity to provide some feedback on the survey and talk in more detail about which aspects are most important to you. This is optional. Should you consent, this will be done as a 30-minute digitally-recorded interview.

To stay in touch for the next rounds of the survey we will ask you for your contact details, but you can update these at any time by letting us know. You also have the option to give us the contact information of a trusted family members who we can speak to in case we cannot reach you directly.

What are the benefits of taking part?

By participating, you are helping us and future young cancer patients get the support they need. Plus, your input could make your future clinic visits more inclusive of what is important to 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 by taking part, if you experience any difficulty because of taking part in this study, please let the study team know who will then support you. You are free to withdraw at any time, with no effect on any of your treatment or care.

Who has reviewed this study?

This study has been reviewed by people who have the experience of cancer themselves and 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 approved by the Research Ethics Committee, a separate 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 to being part of this study, you will be involved for up to three years. After you finish your last survey, 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 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 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 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 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 survey and your 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 recorded and linked to your unique participant number, the recording will be deleted once we transcribe it, removing any information that could identify you.

After you finish your involvement in the study, all the information we collected (survey and clinical information) will be stored in the University of Leeds secure research environment with limited access to specific people in the study team, for 5 years. The anonymised data will be available for future approved research.

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 and 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
- 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>.