



PARTICIPANT INFORMATION SHEET: PARENTS/ LEGAL GUARDIAN

Study title: Autism Spectrum Social Stories™ in Schools Trial 2 (ASSIST2)

We would like to invite you and your child to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it will involve.

One of our team will go through this information with you and answer any questions you may have. You may speak with other people about the study if it will help you decide whether or not to take part.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you want your child to take part.

What is the purpose of the study?

We know that children and young people with autism sometimes struggle with social interaction, communication, behaviour, and interests. These difficulties often cause problems in day to day life and often result in the child or young person feeling socially isolated.

Social Stories™ are an intervention designed by Carol Gray (2000) to help children with Autism Spectrum Disorder (ASD). A story book using pictures and simple language places the child in a story with positive social coping skills. By regularly reading or hearing a story in which they star, the child learns to adopt specific social skills. There has been little research on their use in primary schools. Research to date suggests that it may reduce anxiety or behaviour motivated by frustration but this needs to be researched in a bigger study, which is what we are now doing.

Why have I been chosen?

You have been approached as you are the parent/carer of a child with an Autism Spectrum Disorder who attends a primary school and is between the ages of 4 years and 11 years.

Do we have to take part?

No. It is up to you and your child to decide to take part in the study. You and your child are free to withdraw from the study at any time, without explanation. If you do agree to participate you can stop at any time, without explanation. We will use the information collected so far and stop collecting any further information if you do decide to withdraw. If you decide not to take part in or withdraw from the study this will not stop your child receiving treatment from NHS services in any way.

We will explain the study and go through this information sheet with you. If you agree to take part, we will then ask you to complete and sign a consent form. If your child is able to understand the research, is happy to take part, and can write their name, they will be asked to sign a consent form with you if they would like to.

You will be given a copy of the information sheet and the signed consent/assent forms to keep for your records. Your child is free to withdraw at any time, without giving a reason. This will not affect the care and support your child receives.

What will we have to do and what will happen to my child if we agree to take part?

A researcher will meet with you and your child to discuss the study and take consent if you do want to take part. You will both be asked to set goals with the help of the research team and also complete questionnaires at three times: at the beginning of the study, six weeks into the study and six months into the study. These questionnaires collect information about demographics, the social responsiveness of the child, quality of life and health resource use. The questionnaires at the beginning of the study are the longest, so we recommend that you set aside 90 minutes for this appointment. This amount of time will allow time for breaks and to ask the research assistant any questions you may have as you go along. The questionnaires we would like you to fill in at 6 weeks and 6 months are shorter, so we recommend that you set aside an hour for these appointments. We will also be contacting your child's teacher/teaching assistant to be involved at the same time you and your child will be contacted.

Your child's school will be randomly assigned to either the Social Stories™ intervention, using the new Social Stories™ manual, or to the control arm, which is care as usual by the school. Assignment is decided at random by a computer and children will receive all other treatment or support as usual regardless of allocation. A member of the research team will be observing 20% of participating children in one of their classes. This is to review how close your child is to meeting the goal that was set at the beginning of the study. Agreeing to this is completely optional.

A small group of participants will also be asked to take part in an interview about their experiences of taking part in the study and using the Social Stories™.

We will also ask whether the research team can contact you in the future to follow up this research or to let you know about any other new research projects. Agreeing to this is completely optional. If you agree to this your contact information will be kept on a secure database when the study has finished.

What are the possible disadvantages and risks of taking part?

Some parents may find talking about autism distressing. Some children may not want to read or be involved with Social Stories™. If at any time a participating child feels that the actual or perceived distress is too great they can withdraw from the study. Please don't hesitate to discuss any issues with the research team.

What are the possible benefits of taking part?

Using the Social Stories™ may help your child with their behaviour. This study will provide information about the effectiveness of Social Stories™ for children with autism in primary schools. Free workshops on the writing and use of Social Stories™ will be provided. As a thank you for taking part your family will also receive a £20 voucher.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the research team who will do their best to answer your questions. Contact details for our team are listed at the end of this information sheet.

If you wish to make a complaint (or talk about making a complaint) you can contact the PALS (Patient Advice and Liaison Service) team. They offer confidential and free service to guide you through the different services available at Leeds York Partnership Foundation Trust

Patient Advice and Liaison Service (PALS)

The Becklin Centre
Alma Street
Leeds, West Yorkshire
LS9 7BE
Tel: 0800 052 5790
Email: pals.lypft@nhs.net

If you remain unhappy and wish to complain formally, you can contact:

Sinéad Audsley
Research Manager
Leeds and York Partnership NHS Foundation Trust
Main House
St Mary's House
St Mary's Road
Leeds
LS7 3JX
Tel: 0113 85 54462
Email: sinead.audsley@nhs.net

Dr Stephen Holland - Chair of the University of York's Health Sciences Research Governance Committee
University of York
Heslington
York
YO10 5DD
Tel: 01904 323253
Email: stephen.holland@york.ac.uk

What will happen if we don't want to carry on with the research?

If you withdraw from the research we would still like to know your child's progress. Information collected may still be used. Data will be retained for all participants up to the date of withdrawal, unless you or they specifically request for their data to be removed. We will destroy your child's data and information you have provided, if you wish.

Will taking part in this study be kept confidential?

All information which is collected during the course of the research will be kept strictly confidential. Any information about you or your child will have their name and address removed so that neither of you can be recognised from it. Your child's information may also be looked at by other people involved in the running and supervision of the study to check that it

is being carried out correctly. Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 2018.

Leeds and York Partnership NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will collect information from you and your child for this research study in accordance with General Data Protection Regulation (GDPR) and will act as the Data Controller. This means that we are responsible for looking after your information, using it properly and ensuring this research project is compliant with GDPR. On behalf of Leeds and York Partnership NHS Foundation Trust, the University of York will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change, or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Leeds and York Partnership NHS Foundation Trust will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded to oversee the quality of the study. Individuals from Leeds and York Partnership NHS Foundation Trust and regulatory organisations may look at your research records to check the accuracy of the research study. Leeds and York Partnership NHS Foundation Trust will hold these details along with the information collected from you and your child. The only people in Leeds and York Partnership NHS Foundation Trust who will have access to information that identifies you will be people who need to contact you for follow-ups in the research study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, your child's name or your contact details.

What will happen to the results of the research study?

When the study has finished we will present our findings at conferences and we will put the results in research papers and on websites so that it can inform future support for children with autism. All data that is publicised will be anonymous, which means that you or your child will not be identifiable.

We will also contact all participants involved in the study to let them know the results of the research. Newsletters will also be sent out to all participants throughout the study.

Who is organising and funding the research?

The research is being organised by Leeds and York Partnership NHS Foundation Trust. It is being paid for by NIHR Health Technology Assessment (HTA). ASSSIST2 receives statistical/health economic analysis support and health research expertise from the Clinical Trials Unit and the Department of Health Sciences at University of York

Who has reviewed the study?

This study has been reviewed and given a favourable ethical opinion by North East - York Research Ethics Committee (REC Reference: 19/NE/0237). It has also been approved by the Health Research Authority (HRA) and Health Sciences Research Governance Committee, University of York.

Contact for further information

integrity | simplicity | caring

If you would like any further information about this study contact:

Dr Jane Blackwell
Research Fellow / Trial Coordinator
COMIC research, 2nd floor IT Centre,
Innovation Way, Heslington,
York, YO10 5NP
Tel: 01904 294279
Email: jane.blackwell2@nhs.net

Dr Kerry Bell
Research Fellow / Trial Coordinator
Department of Health Sciences,
University of York, Heslington,
York, YO10 5DD
Tel: 01904 321325
Email: Kerry.bell@york.ac.uk

If you and your child decide to take part in this study, you will be given this information sheet and signed consent and assent forms to keep.

Thank you for taking the time to read this information sheet.