

Supplementary Materials 1: Information Sheets



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)

[DETAILS]

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

[SPONSOR DETAILS]

or

[CHAIR OF THE UNIVERSITY OF YORK'S HEALTH SCIENCES RESEARCH GOVERNANCE COMMITTEE
DETAILS]

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). ASSIS2 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

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

[TRIAL COORDINATOR DETAILS]

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.



PARTICIPANT INFORMATION SHEET: CHILDREN

We are asking you and your family to take part in helping us answer this question:

Will reading Social Stories™ help children with autism socially and emotionally?

Before you decide if you want to join in, it is important that you understand what the study is about, why the study is being done and what it will mean if you take part. Please read this leaflet carefully with your family.

If something doesn't make sense or if you have any questions you can ask your parents to give us a call and we can discuss it with you and your family.

Why are we trying to answer this question?

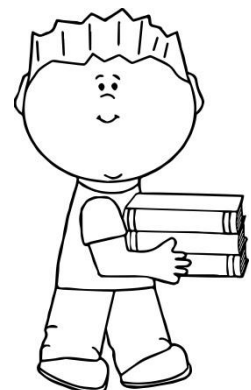
Sometimes, children with autism find it hard to play with other children or express their emotions. This might make them feel upset, angry, or very worried. Even though it is normal to have these feelings, some children might need some help so they can play happily with friends. We want to find out if reading Social Stories™ is a good way to help with this.

Why have I been asked to take part?

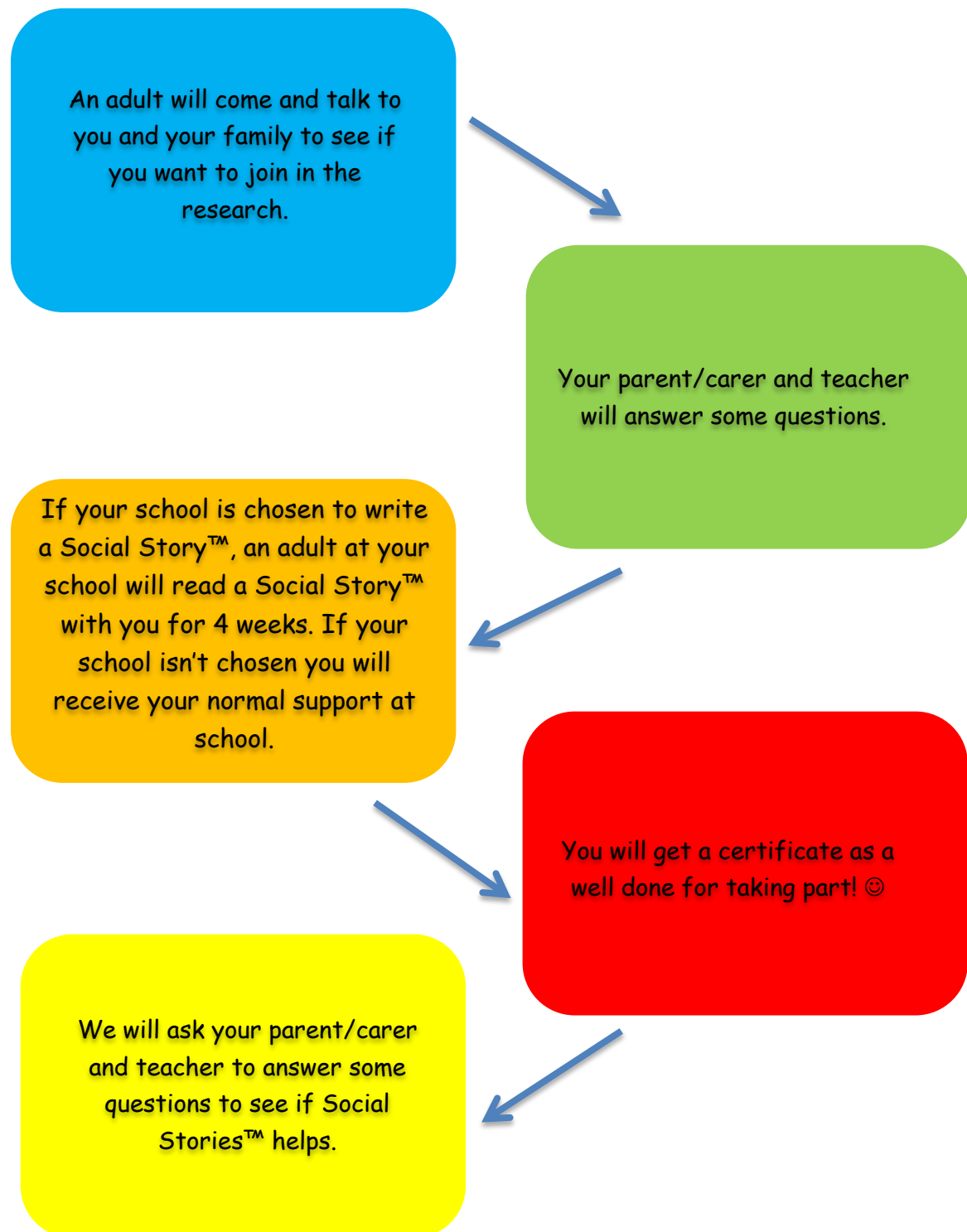
You have been asked to take part because you might enjoy reading Social Stories™ at school.

Do I have to take part?

No. It is your choice to take part in the study. If you decide to take part but then want to stop that is fine. You can stop whenever you want, just tell your parent or teacher.



What will happen to me if I take part?



What happens?

Not all schools will take part in writing and reading a Social Story™ because we want to see if Social Stories™ work. If your school is chosen for Social Stories™ a teacher or teaching assistant you know at your school will read a

Social Story™ to you at least 6 times over 4 weeks. After the last session your school may not choose to continue using Social Stories™.

A researcher may also come to your school to watch one of your classes.

If your school isn't selected to write and read a Social™ Story we will ask your teacher and parent/guardian some questions later on and you won't have to do anything else.

What if there is something that you do not like?

If there is a problem you can talk to your parents, teachers at school or any of the researchers.

Thank you for reading this form - you can ask us any questions you like.



PARTICIPANT INFORMATION SHEET: TEACHERS

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

This leaflet lets you know about our study if you are considering taking part. It explains why the research is being done and what it will involve.

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 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 Social Story™ is 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 teacher or teaching assistant of a child with an Autism Spectrum Disorder in a primary school who is between the ages of 4 years and 11 years.

Do we have to take part?

No. Participation is entirely voluntary and it is up to you whether or not you would like to participate. You 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 the child receiving treatment from NHS services in any way.

What will I have to do?

A researcher will visit the school to discuss the study and take consent if you do want to take part. Parents and teachers will 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. To allow time for the questionnaire and setting

the goal we recommend that you set aside 60 minutes for the first appointment. The questionnaires we would like you to fill in at 6 weeks and 6 months are shorter, but may take up to 30 minutes to fill in.

Your school will be randomly assigned to either the Social Stories™ intervention, using the Social Stories™ manual, or to the control arm, spending the equivalent amount of time reading a story of similar length. Assignment is decided at random by a computer and children will receive all other treatment or support as usual regardless of allocation.

A small group of participants will be asked to take part in an interview about their experiences of taking part in the study and using the Social Stories™. These interviews will be audio recorded. Only researchers working on this study will have access to the audio recordings and they will be stored on an encrypted computer.

If your school is assigned to the group using Social Stories™ we will arrange for the teacher or TA who will administer the Social Stories™ (referred to as the interventionist) to attend a free workshop on the writing and use of Social Stories™ and provide them with a free manual on Social Stories™. If your school is assigned care as usual, the interventionist will not be able to attend this workshop or receive the manual initially but both will be provided at the end of the study. Professor Barry Wright and other researchers will be available should you require further assistance or advice.

A member of the research team will be observing 20% of participating children in one of their classes. This is to review how close the child is to meeting the goal that was set at the beginning of the study. Agreeing to this is completely optional.

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 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 the child you teach 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.

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 are listed at the bottom of this 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

[PALS DETAILS]

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

[SPONSOR DETAILS]

[CHAIR OF THE UNIVERSITY OF YORK'S HEALTH SCIENCES RESEARCH GOVERNANCE DETAILS]

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

If you withdraw from the research we would still like to know how the child is progressing. If you do not want to continue being involved in the research we will ask the school if there is another teacher that could complete the associated questionnaires and interview (if applicable). We will still ask the parent/carer and the child if they are happy to continue to complete the questionnaires. Data will be retained for all participants up to the date of withdrawal, unless they specifically request for their data to be removed.

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 will have your name and address removed so that you cannot be recognised from it. Your 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 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. 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 or 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 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 Foundation Partnership NHS 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.

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

[TRIAL COORDINATOR DETAILS]

If you decide to take part in this study you will be given this information sheet and a signed consent form to keep.

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



PARTICIPANT INFORMATION SHEET: INTERVENTIONISTS

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

This leaflet lets you know about our study if you are considering taking part. It explains why the research is being done and what it will involve.

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 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 teacher of a child with an Autism Spectrum Disorder in a primary school who is between the ages of 4 years and 11 years.

Do I have to take part?

No. Participation is entirely voluntary and it is up to you whether or not you would like to participate. You 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 the child receiving treatment from NHS services in any way.

What will I have to do?

You will only take part in the research if your school is randomised to the Social Stories™ intervention.

A researcher will visit the school to discuss the study and take consent if you do want to take part. Your role would be to deliver the intervention and to complete questionnaires at three times: at the beginning of the study, six weeks into the study and six months into the

study. The questionnaire at the beginning of the study is about you and your teaching experience, the 6 weeks and 6 months questionnaires are about your experience using Social Stories™, whether you are still using them and if so why/why not. The questionnaires should take around 15 minutes to complete at each of the time points.

Your school will be randomly assigned to either the Social Stories™ intervention, using the Social Stories™ manual, or to the control arm, care as usual. Assignment is decided at random by a computer and children will receive all other treatment or support as usual regardless of allocation.

A small group of participants will be asked to take part in an interview about their experiences of taking part in the study and using the Social Stories™. These interviews will be audio recorded. Only researchers working on this study will have access to the audio recordings and they will be stored on an encrypted computer.

If your school is assigned to the group using Social Stories™ we will organise for you to attend a free workshop on the writing and use of Social Stories™ and provide you with a free manual on Social Stories™. If you are assigned to the care as usual group, you will not be able to attend this workshop or receive the manual *initially* but both will be given to the school after the last questionnaires have been completed (after 6 months). Professor Barry Wright and other members of the research team will be available should you require further assistance or advice.

A member of the research team will be observing 20% of participating children in one of their classes. This is to review how close the child is to meeting the goal that was set at the beginning of the study. Agreeing to this is completely optional.

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 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 the child you teach 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.

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 are listed at the bottom of this 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

[PALS SERVICE DETAILS]

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

[SPONSOR DETAILS]

[CHAIR OF THE UNIVERSITY OF YORK'S HEALTH SCIENCES RESEARCH GOVERNANCE DETAILS]

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

If you withdraw from the research we would still like to know how the child is progressing. If you do not want to continue to deliver the intervention we will ask the school if there is another teacher that could deliver the therapy and complete the associated questionnaires and interview. We will still ask the parent/carer and the child if they are happy to continue to complete the questionnaires. Data will be retained for all participants up to the date of withdrawal, unless they specifically request for their data to be removed.

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 will have your name and address removed so that you cannot be recognised from it. Your 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.

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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.

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