The Department of Health Sciences

Autism Spectrum Social Stories™ In Schools Trial 2 (ASSSIST2)

Study Protocol

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Sponsor: Leeds and York Partnership NHS Trust

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Trial Summary

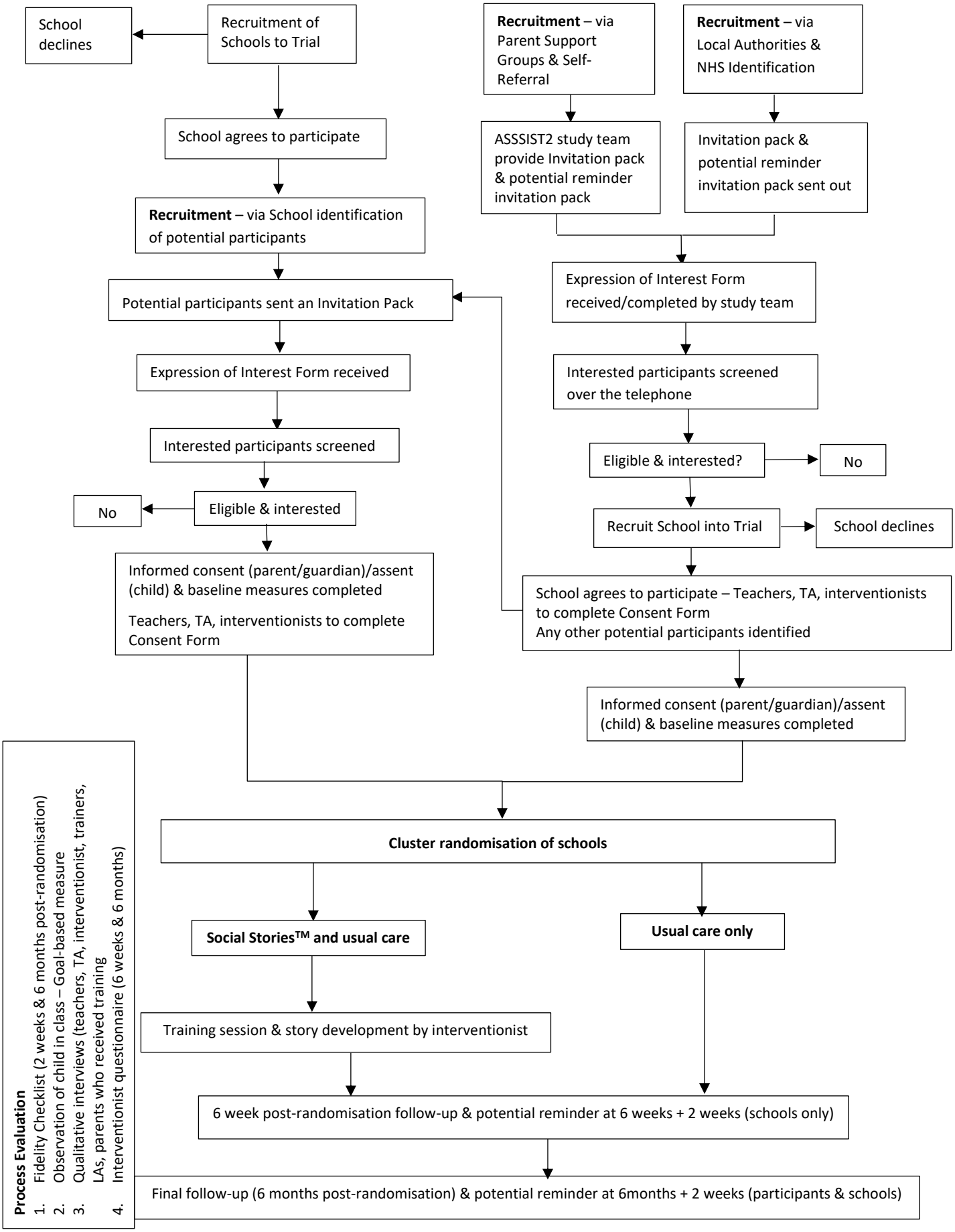
TITLE	Autism Spectrum Social Stories™ In Schools Trial 2	
ACRONYM	ASSSIST2	
Protocol Version **Date** **ISRCTN** **IRAS** **NIHR HTA**	**Version 1.11** **4th December 2019** **ISRCTN11634810** **251805** **16/111/91**	
Methodology	Pragmatic cluster randomised controlled trial with an internal pilot	
Study Duration	42 months	
Study Centres	Schools and NHS Trusts across England	
Objective	To establish whether Social Stories™ are clinically and cost-effective in improving child social responsiveness, reducing challenging behaviour and improving social and emotional health in children with ASD in primary schools	
Primary Outcome	Social Responsiveness Scale (SRS-2) at 6 months completed by the associated teacher.	
Secondary outcomes	Completed by parent/guardian: SRS-2 score; The Revised Children Anxiety and Depression Scale (RCADS); Parental Stress Index Short Form; The EQ-5D-Y collected by proxy; Resource use; Preference Questionnaire	Completed by associated teacher: SRS-2 score; Goal-based outcome measure; Resource use; Preference Questionnaire
Number of Subjects/Patients	278 children (alongside 278 parents/guardians, 278 associated teachers, and 139 interventionists) will be recruited (n=139 to Social Stories™ with care as usual and n=139 to vs care as usual only). Allowing for a 25% attrition rate we expect data to be successfully collected on 208 children. Randomisation will be stratified by school type (SEN vs non-SEN) and number of consented children in the school (≤5 vs >5).	
Main Inclusion Criteria	Children diagnosed with autism spectrum disorder (ASD) aged 4-11 years old.	
Statistical Analysis	Primary and key secondary outcomes will be analysed using mixed models incorporating outcomes collected at all follow-up time-points; adjusting for the baseline measure, baseline characteristics (e.g. age, sex, etc), randomisation group and stratification factors as fixed effects; and school as a random effect.	

Abbreviation List and Glossary

ADHD:	Attention deficit hyperactivity disorder
AE:	Adverse Event
ASCEND:	Autism Spectrum Conditions - Enhancing Nurture and Development
ASD:	Autism Spectrum Disorder
Associated teacher:	A member of school staff who completes questionnaires about children from their school participating in the study
ASSSIST2:	Autism Spectrum Social Stories™ In Schools Trial 2
CAMHS:	Child and Adolescent Mental Health Services
CAU:	Care as Usual
CI	Chief Investigator
CTU:	Clinical Trials Unit
DMEC:	Data Monitoring and Ethics Committee
EHCP:	Education Health Care Plan
EQ-5D-Y:	European Quality of Life-5 Dimension
GP:	General Practitioner
HRA:	Health Research Authority
HTA:	Health Technology Assessment
IAPT:	Improving Access to Psychological Therapies
IEP:	Individual Education Plan
ILP:	Individual Learning Plan
Interventionist:	A member of school staff who will deliver the intervention
ITT:	Intention To Treat
NHS:	National Health Service
NICE:	National Institute for Health and Care Excellence
NIHR:	National Institute for Health Research
NPT:	Normalisation Process Theory
PIS:	Participant Information Sheet
PPI:	Patient and Public Involvement
QALY:	Quality-Adjusted Life Years
RA:	Research Assistant
RCT:	Randomised Controlled Trial

SAE:	Serious Adverse Events
SENCO:	Special Educational Needs Co-ordinator
SOP:	Standard Operating Procedure
TA:	Teaching Assistant
TMG:	Trial Management Group
TSC:	Trial Steering Committee
UK:	United Kingdom

Trial Flow Chart



1. Background

1.1. Autism Spectrum Disorder

Autism Spectrum Disorder (ASD) is a lifelong neurodevelopmental disorder that affects up to 1.6% of children in the UK and has an adverse impact on overall adult outcome (Baron-Cohen *et al.,* 2009; Howlin & Moss, 2012). Children with ASD are characterised by qualitative impairments in social communication, rigidity of thought, restricted interests and stereotyped behaviours (American Psychiatric Association, 2013). Teachers in primary schools often face challenges with the education of children with ASD in their classroom (Simpson et al., 2003). Children with ASD are less able to intuitively understand how they are expected to behave or to learn social rules by observing others as their typically developing peers might do (Travis et al., 2001). Many children with autism struggle to manage social anxiety, feelings of anger, and this can lead to outbursts of aggression (White et al., 2012). Social communication difficulties are frequently associated with persistently disruptive behaviour (Donno et al., 2010). As an aggravating factor, teachers face many demands on their time in the classroom and may not be able to focus enough on the child's needs for them to achieve their full educational potential. One intervention that attempts to alleviate these social difficulties whilst not being intrusive, time consuming or requiring extensive involvement of outside experts is Carol Gray's Social Stories™ (Scattone & Tingstrom, 2006).

Social Stories™ are short stories which describe a social situation or skill to help children with ASD to understand a situation applicable to the child more easily. They write a child into their own story about themselves to help them learn new social information. They are commonly used to enable children to understand socially expected behaviours and norms. Social Stories™ are defined by ten criteria which guide story development. Their original designer, Carol Gray, believes these criteria are the hallmark of their success (Gray, 2010). The criteria guide story development to ensure an overall patient, supportive quality and relevant content that is descriptive, meaningful and safe for the audience. These stories are written in a specific way using a variety of defined sentence types and a formula for the ratio of sentences in a social story. Using this formula and framework suggested by Carol Gray, Social Stories™ can be a flexible intervention that can be individualised to different social situations and children with ASD. The capacity for tailoring these stories is particularly important for helping a child with ASD as they are a very heterogeneous group exhibiting different strengths and deficits (National Research Council, 2001; Ivey et al., 2004).

Research has examined Social Story™ use both in special education (Crozier & Tincani, 2007) and mainstream education settings (Delano & Snell, 2006), as well as their application within the home (Ivey et al., 2004). Much of this research on Social Stories™ has shown positive results (Chan & O'Reilly, 2008). Through use of this intervention, children with ASD have shown improvements in social interactions (Norris & Dattilo, 1999; Barry & Burlew, 2004), decision making (Barry & Burlew, 2004), voice volume (Ozdemir, 2008) and mealtime skills (Bledsoe et al., 2003). Success has also been reported in addressing disruptive behaviours, including reducing tantrums (Lorimer et al., 2002; Kuttler et al., 1998) and behaviours associated with frustration (Adams et al., 2004).This research also suggests that it is possible to train tier one professionals, for example teachers, in the use of developing Social Stories™ tailored to a child, and for these stories to benefit children with ASD (Quilty, 2007). Despite this research, two systematic reviews of their effectiveness (Kokina & Kernm, 2010; Reynhout & Carter, 2006) indicate a number of gaps in the literature. The reviews identified largely single case designs and a paucity of good quality, comparative evidence on Social Stories™. There are to date no good quality fully powered randomised controlled trials and this study seeks to address this.

1.2. Rationale

Children with ASD have a higher prevalence of mental health problems than typically developing children, including anxiety and low mood (Kim et al, 2000), disruptive (Koegel et al., 1992), and repetitive behaviours (Turner, 1999). Research shows that severe social difficulties represent a cost to the NHS and social care across childhood and adulthood (NICE, 2013; National Audit Office, 2009).

Research surrounding Social Stories™ are purported to promote calmer classrooms with improved learning/better integration in special (Crozier & Tincani, 2007) and mainstream (Delano & Snell, 2006) education settings, and improved social behaviours (Ivey et al, 2004). Using Social Stories™, children with ASD have shown improvements across a range of behaviours including social interaction (Norris & Dattilo, 1999), decision making (Barry & Berlew, 2004), reduced disruptive behaviours, tantrums and frustration (Lorimer et al, 2002; Adams et al, 2004).

It is possible to effectively train school-based professionals in the use and writing of Social Stories™ tailored to a child (Quilty, 2007; Wright et al., 2016). This research is needed now because numerous schools employ a Social Stories™ intervention despite the fact there is no clear evidence base for its effectiveness. This RCT would comprehensively address this deficit.

As described previously, research to date shows promise across a range of behaviours. As part of the feasibility study we conducted a systematic review (Wright et al., 2016). The vast majority of studies were single case studies (N=77) with positive outcomes. There were four small studies using some form of randomisation to allocate participants to a Social Story™ or control condition that showed positive results (Andrews, 2005; Bader, 2006; Feinberg, 2001; Quirmbach et al., 2009) but with methodological limitations. Our successful feasibility RCT found promising evidence of effectiveness and cost-effectiveness in 50 participants across 37 schools (Wright et al., 2016), with high participant satisfaction and good outcome completion rates, and a fully powered RCT is now warranted.

This is highly relevant in a climate where there have been reduced resources for children with neurodevelopmental problems and mental health problems both from a reduction in funding within Local Authorities but also from a reduction in funding within the NHS. Given that specialist teacher or specialist clinical psychology, child psychiatry or child mental health practitioner interventions are less available, interventions such as Social Stories™ deserve robust evaluation. This is because they can be delivered within schools by teaching staff on a day to day basis and may potentially reduce the need for specialist referral elsewhere. We will be exploring these aspects within our study.

2. Trial Summary

This study is a randomised controlled trial (cluster randomised by school) to assess whether Social Stories™ is clinically and economically cost-effective in improving child social impairment, reducing challenging behaviour and improving social and emotional health in children with ASD in primary schools.

A previous feasibility study has been carried out to develop a treatment manual, training materials and to test recruitment across schools and the NHS (Wright et al, 2014; Marshall et al, 2016; Wright et al, 2016). For this new phase of the study we will recruit:

- 278 4-11 year old primary school children with a diagnosis of ASD in England;
- 278 parents/carers;
- 278 associated teachers;
- 139 interventionists.

The primary follow-up will be 6 months post randomisation. An internal pilot (first 10 months of recruitment) will be carried out to demonstrate satisfactory recruitment progress. At the end of the pilot we expect to have recruited n=110 participants of which one third (n=44) will have reached final follow-up (6 months post-randomisation). There will be a nested economic evaluation, qualitative component and fidelity assessment.

3. Objectives

3.1 Primary Objective

To establish whether Social Stories™ can improve social responsiveness in children with ASD in primary schools.

3.2 Secondary Objective

The secondary objectives of this trial are:

1. To investigate whether Social Stories™ can reduce challenging behaviours (e.g. reduction in head-banging or severe tantrums) in children with ASD in primary schools.
2. To investigate whether Social Stories™ can improve social and emotional health in children with ASD in primary schools.
3. To assess the cost-effectiveness of Social Stories™.
4. To examine the effects of Social Stories™ delivered in the classroom on general measures of health related quality of life.
5. To examine whether Social Stories™ improve classroom attendance and reduce expensive out of area placements.
6. To assess sustainability of Social Stories™ in an education system across a 6 month period.
7. To examine improvements in parental stress levels.
8. To examine how treatment preference links to outcome success.
9. To examine how elements of session delivery (e.g. session frequency, length and any associated problems/adverse events) link to outcome success.

4. Outcome Measures

A range of measures will be used throughout the ASSSIST2 trial in order to investigate the primary and secondary objectives (see Table 1 for how outcomes map onto specific objectives, and Tables 2-4 for an overview of outcome measures and time-points). Follow up booklets can be completed by participants either via post or during a face to face visit with a research assistant.

Table 1: Objectives and outcome measures:

	Objective:	Outcome measure:
Primary	Improve child social responsiveness	Social Responsiveness Scale (SRS-2)
Secondary	1. Reduce challenging behaviours	Bespoke goal-based outcome measure (validated with blinded observation of 20% of participants in a classroom setting by research assistants at 6 weeks and at 6 months).
	2. Improve social and emotional health	Revised Children Anxiety and Depression Scale (RCADS) short form
	3. Cost-effectiveness of Social Stories™	A bespoke resource use questionnaire
	4. Improve health related quality of life	a) Bespoke health care resource use questionnaire b) EQ-5D-Y proxy
	5. Improve parental stress levels	Parental Stress Index (PSI) short form
	6. Improve classroom attendance and reduce expensive out of area placements	A bespoke questionnaire to determine current school care/education plan interventions and support provided to the child in class
	7. Sustainability of Social Stories™	A bespoke Social Stories™ sustainability questionnaire
	8. To examine how treatment preference links to outcome success.	A bespoke preference questionnaire prior to randomisation asking which they would prefer. This will enable us to analyse preference against outcome.
	9. To examine how elements of session delivery (e.g. session frequency, length and any associated problems/adverse events) link to outcome success.	A bespoke Social Stories™ session log capturing frequency, length and times; problems or adverse events in the context of delivery.

Table 2: Study Assessment Schedule 1: Outcome measures to be completed by parents/guardians throughout the ASSSIST2 trial

PARENT/GUARDIAN ASSESSMENTS	Consent	Baseline Assessment	6 week Follow-up Assessment	6 month Follow-up Asseessment
Consent	X			
Child Assent (where possible)	X			
Demographics		X		
Questionnaires • Social Responsiveness Scale-2 • Parental Stress Index Short Form • EQ-5D-Y (proxy) • RCADS • Health care resource use • Preference Questionnaire		X X X X X X	X X X X	X X X X X

Table 3: Study Assessment Schedule 2: Associated teacher/teaching assistant outcome measures

ASSOCIATED TEACHER/TA ASSESSMENTS	Consent	Baseline Assessment	6 week Follow-up Assessment	6 month Follow-up Asseessment
Consent	X			
Demographics	X			

Questionnaires • Social Responsiveness Scale-2 • Goal-based Outcome Measure • Health care resource use • Current school care/education plan interventions Questionnaire • Preference Questionnaire		**X** **X** **X** **X** **X**	**X** **X**	**X** **X** **X** **X**

Table 4: Study Assessment Schedule 3: Interventionist outcome measures

INTERVENTIONIST TEACHER/TA ASSESSMENTS	**Consent**	**Baseline Assessment**	**During Intervention Delivery**	**6 week Follow-up Assessment**	**6 month Follow-up Asseessment**
Consent	**X**				
Demographics		**X**			
Questionnaires • Sustainability Questionnaire • Social Story™ session log (completed after each session)			**X**	**X**	**X**

4.1 Primary outcome

The primary outcome is the Social Responsiveness Scale (SRS-2) completed by the associated teacher/TA at 6 months post-randomisation, which measures social impairment, ASD symptomatology and social interaction skills.

4.2 Secondary outcomes

All secondary outcome measures will be collected at baseline, 6 weeks and 6 months post-randomisation unless otherwise stated.

4.2.1. Parent questionnaires

1. Social Responsiveness Scale (SRS-2) (Constantino & Gruber, 2012) (further details in Section 4.1).
2. Demographic information pertaining to the child and the parent.
3. Parental Stress Index short form, which evaluates the parenting system and identifies issues that may lead to problems in the child's or parent's behaviour (Abidin, 2012).

4. The EQ-5D-Y (proxy) (The EuroQol Group, 1990), a five item generic preference-based measure of health-related quality of life that allows a proxy person to complete the measure for the participant.
5. Revised Children Anxiety and Depression Scale (RCADS) short form, a child mental health outcome measure for anxiety and depression (Chorpita et al, 2000).
6. Bespoke resource use questionnaire, which captures the healthcare and non-health resource implications (including costs in the education sector, and costs of productivity loss and out-of-pocket expenditures for parents) attributable to the child's difficulties due to their condition).
7. Bespoke preference questionnaire.

4.2.2. Associated teacher/TA questionnaires

1. Social Responsiveness Scale (SRS-2) (Constantino & Gruber, 2012) (further details in section 4.1).
2. A goal-based outcome measure (adapted from the Child Outcomes Research Consortium).
3. A bespoke resource use questionnaire.
4. A bespoke preference questionnaire.
5. A bespoke questionnaire to determine current school care/education plan interventions that has been used in previous child autism research by this group.

4.2.3. Interventionist Teacher/ TA Questionnaires

1. A bespoke sustainability questionnaire with all participating teachers asking how many times they have used the intervention with the same child and/or different children; and whether they have trained other teachers (if they have been trained to train). We will use a fidelity checklist of all written Stories, and record satisfaction ratings.
2. A Social Story™ session log used to record frequency, length and times; problems or adverse events in the context of delivery.

4.2.4. Process Evaluation - Researcher Questionnaires

1. A fidelity checklist on each Social Story™ (intervention arm only) will be used to assess each Social Story™ after the story has been created and at 6 weeks post-randomisation.
2. At 6 weeks and 6 months post-randomisation a researcher will complete a goal-based measure when observing 20% of the children in a classroom setting. This researcher will be blinded to intervention allocation. Consent to these observations will be optional and participants will be randomly selected to be observed from those who have opted in.

5. Study Design and Setting

The current trial will only include primary schools as a previous systematic review (Wright et al., 2016) found the majority of evidence pertains to primary school age children and the qualitative interviews corroborated that it is better suited to children of primary school age. However, as this study involves both mainstream and special educational needs (SEN) schools, we will take a pragmatic view on the definition of primary school. As SEN schools often have a different structure than mainstream schools, there will be occasions where a SEN school participant will move from year 6 to year 7 without there being a change to any practical or environmental circumstances likely to influence intervention delivery (i.e. they will be in the same school, same

class, and have the same teachers). If a participant in this situation wishes to be part of the trial, we will consent them to the trial as if they were to remain a primary school student throughout their participation in the research.

This is a multi-site pragmatic cluster RCT comparing Social Stories™ and care as usual with a control group receiving care as usual alone. Care as usual is defined as the existing support routinely provided for a child with ASD from educational services. The trial includes a 10 month internal pilot, a process evaluation (including qualitative interviews and an examination of treatment fidelity) and an economic evaluation.

There are two main routes into the trial. Participants will either be:

- identified and/or recruited via their school; or

- identified through participating NHS Trusts using their clinic lists/databases.

Intervention delivery will take place in the child's school. Baseline and follow-up visits will take place within schools, participants home or at a location convenient for participants.

5.1 Internal Pilot

The RCT will include an internal pilot which will be the first 10 months following the start of recruitment. At the end of this period, the trial team will report to the TSC and DMEC so they can review the feasibility of continuing recruitment based on previously agreed Stop/Go criteria.

Stop/Go criteria will be based on the feasibility of recruitment, retention and safety outcomes. We anticipate a recruitment rate of 11 children per month. At ten months, we would have expected to recruit 110 children, and we will include a stopping criterion of 100% of the recruitment target n=110. One third of the recruited participants would have completed final follow-up (n=44). If the trial is halted, all remaining participants will continue to be followed up until 6 months post-randomisation.

6. Eligibility Criteria

Parents/guardians will be invited to participate in the trial if they meet the following criteria.

6.1 Inclusion criteria

A participant will be included if:

- The child is aged 4-11 years.
- The child attends a participating school in Yorkshire and Humber.
- The child has a clinical diagnostic criteria diagnosis of ASD and daily challenging behaviour.
- Parents/guardians of the child are able to self-complete the English language outcome measures (or complete with assistance)
- The child is willing to give assesnt and the parent/guardian is able to give consent

6.2 Exclusion criteria

A participant will not be included if:

- The school has used Social Stories™ for any pupil in the current or preceding school term.

- The child or interventionist teacher has taken part in the ASSSIST feasibility study. We will not exclude schools that have taken part.
- The parent/guardian is unable to fill in the questionnaires (e.g. they cannot understand the questionnaire)

7. Trial Procedures

7.1 Recruitment

ASSSIST2 will use five methods of participant recruitment:

1. School identification of potential participants
2. Local community groups e.g. parent support groups
3. Liaising with Local Authority professionals
4. Local parents contacting the research team
5. NHS Trusts via database/clinic list identification

These methods are outlined in more detail below.

7.1.1. Recruitment from schools

For a child to participate in the trial the school will also need to agree to participate, as the intervention is delivered in school and some outcomes measures are collected in schools (see Tables 3 & 4). There are several routes by which the child and school may agree to be part of the trial. Schools will be approached with information about the trial and if the school expresses an interest, the study will be discussed with an appropriate member of the school (e.g. a head teacher or a Special Educational Needs Co-ordinator (SENCO). Once a school has agreed to participate in the trial they will be asked to send an Invitation Pack (Invitation Letter, Participant Information Sheet, Child Participant Information Sheet, an Expression of Interest Form and stamped addressed envelope) to parents/guardians of eligible children at the school.

In identifying schools it has been noted that some areas have schools that are closely linked, i.e. infant and junior schools. These shall be treated as two separate schools for the purposes of recruitment unless there is a notable risk of research contamination across sites because:

- they are situated on the same geographical site;
- they are situated on different geographical sites but share the same head teacher and SENCO, and where any of the teaching staff working directly with children on the autism spectrum work on both sites.

In these circumstances they will be considered as one site for recruitment and randomisation.

Schools will be asked to send a Reminder Invitation Pack to parents/guardians where an Expression of Interest Form has not been received by the study team, approximately 4 weeks after the original invitation pack has been sent out.

7.1.2. Recruitment from parent support groups

Local parent support groups, such as the Autism Spectrum Conditions - Enhancing Nurture and Development (ASCEND) parent group (Pillay *et al.,* 2011) in York, will be a contacted about the

trial. The research team will offer to give presentations and share leaflets about the research with autism support groups. Invitations Packs (Invitation Letter, Participant Information Sheet, Child Participant Information Sheet, an Expression of Interest Form and stamped addressed envelope) will be given to interested parents. It will be made clear that participation is dependent on the school taking part in the research. For parents who have completed the Expression of Interest Form, the school will then be contacted to inform them about the study and to identify the Social Stories™ status of the school and the child. Once contact has been established with the school, the research team will follow the same recruitment procedure as outlined in Section 7.1.1.

7.1.3. Recruitment from liaising with Local Authority professionals

We will contact relevant professionals within the local authority such as the educational specialist in ASD. This individual will be asked to contact the parents/guardians of potentially eligible children with and Invitation Pack (Invitation Letter, Participant Information Sheet, Child Participant Information Sheet, an Expression of Interest Form and stamped addressed envelope). If an Expression of Interest Form is returned the study team will contact the parent/guardians directly to establish eligibility and the child's school will be contacted, the research team will then follow the same recruitment procedure outlined in Section 7.1.1. The educational specialists will also be able to inform the research team when new diagnoses are given to children at schools previously found to be ineligible due to having no children with ASD on their register at the time of contact. The research team will then contact the school directly and follow the recruitment procedure outlined in Section 7.1.1.

7.1.4. Recruitment from local publicity

We are aware that some local eligible families may hear about the trial from a range of sources and contact the research team to express their interest. If a local family contacts the research team, they will confirm the child's eligibility and send them an Invitation Pack (Invitation Letter, Participant Information Sheet and Child Participant Information Sheet), it will be made clear that participation is dependent on the school taking part in the research. The researcher will complete an Expression of Interest Form on the family's behalf. The research team will then contact the school directly and follow the recruitment procedure outlined in Section 7.1.1.

7.1.5 Recruitment from NHS sites

Participating NHS Trusts who carry out autism assessments will be asked to identify potentially eligible children and their families. Trusts will be asked to screen their clinic/database lists of potentially eligible children. Once identified, a member of the clinic team (or delegated member) at the Trust will send an Invitation Pack (Invitation Letter, Participant Information Sheet, Child Participant Information Sheet, an Expression of Interest Form and stamped addressed envelope) to the parent/guardian for the child. If the parent/guardian return an Expression of Interest Form a member of the research team will contact them to discuss the project further, it will be made clear that participation is dependent on the child's school taking part. The research team will then contact the school directly and follow the recruitment procedure outlined in Section 7.1.1. Trusts will be asked to send a Reminder Invitation Pack to parents/guardians where an Expression of Interest Form has not been received by the study team, approximately 4 weeks after the original invitation pack has been sent out.

7.2 Screening and Eligibility Checks

Research assistants will contact all families who have completed an Expression of Interest Form by telephone to screen participants for eligibility using the eligibility criteria outlined in Section 6. Where contact is not initially possible we will make use of information indicated on the Expression of Interest Form about preferred mode of contact and will contact them up to 4 times by email, text letter or telephone.

If a child is potentially eligible for inclusion after confirming a diagnosis of ASD with parents / guardian on the phone, the research assistant will arrange a face-to-face visit in order to take informed consent, child assent and complete baseline CRFs. Any child who does not meet the eligibility criteria for study participation and/or do not assent to the trial will be signposted to alternative sources of help relevant to their local area.

7.3. Informed Consent

Participation in the study will be entirely voluntary and written informed consent from participants will be obtained before baseline data is collected and randomisation is conducted. Given the age and client group, informed consent will be obtained from the parent/legal guardian and assent will be obtained from the child (where possible). Where a child declines to participate we will not include them as the intervention requires co-operation.

Written consent will also be obtained from teachers/TAs and interventionists.

The study team will also seek consent from teachers/TAs, local authority contacts and others who have been involved in the intervention delivery in order for them to be included in interviews for the qualitative study.

7.4 Randomisation and Allocation

7.4.1. Randomisation

Randomisation will occur after consent has been obtained and baseline measures collected from parents and education professionals to ensure allocation concealment to prevent selection bias. We will use a cluster randomisation process to allocate participating schools to Social Stories™ intervention and usual care or usual care alone (1:1). Randomisation will be stratified by school type (SEN vs non-SEN) and number of consented children in the school (≤5 vs >5).

7.4.2 Method of implementing the allocation sequence

Randomisation and allocation to arms will be conducted using the remote, centralised secure randomisation service provided by York CTU. Once allocation is made, the trial manager will inform the school of their status by phone or email. We will request that the school schedules the 4 week intervention sessions as soon as the interventionist is trained to deliver the Social Stories™ intervention to ensure that they will be delivered before the 6 week follow-up point. A letter with this information and details on what their particular allocation involves will also be sent to both the school and the parents of participating children at that school after randomisation. This process has been examined and proved effective in a previous school based study involving children with ASD (Wright *et al.,* 2016).

8. Study Intervention

8.1 Social Stories™

Social Stories™ are short stories which describe a social situation or skill to help children with ASD to understand a situation applicable to the child more easily. They write a child into their own story about themselves to help them learn new social information. They are commonly used to enable children to understand socially expected behaviours and norms. Social Stories™ are defined by ten criteria which guide story development. Their original designer, Carol Gray, believes these criteria are the hallmark of their success (Gray, 2010). The criteria guide story development to ensure an overall patient, supportive quality and relevant content that is descriptive, meaningful and safe for the audience. These stories are written in a specific way using a variety of defined sentence types and a formula for the ratio of sentences in a social story. Using this formula and framework suggested by Carol Gray, Social Stories™ can be a flexible intervention that can be individualised to different social situations and children with ASD. The capacity for tailoring these stories is particularly important for helping a child with ASD as they are a very heterogeneous group exhibiting different strengths and deficits (Committee on the Educational Interventions for Children with Autism, 2001; Ivey et al., 2004).

The Social Stories™ intervention (according to the Carol Gray criteria) is much broader than just reading a story with social information to the child. One of these criteria specifically states that the people who know the child best (like class teachers, TAs and parents) meet to talk together and discuss the behaviour in question from a point of view of understanding the child's perspective. In our Social Stories™ workshop (given to all schools randomised to the intervention) this is exactly what we do. Associated teachers, interventionists, and participating parents who are able to attend the training are encouraged to try to think more carefully about why a child is behaving in a particular way, what additional information a child may need to help them learn to be part of the classroom group or to feel less anxious in social situations. This guided and structured way of talking about and assessing the child's behaviour adds value to the Social Story™ itself. The Carol Gray Social Stories™ intervention is therefore far more comprehensive than the reading of the story itself.

Participating children allocated to the intervention group will have delivered to them a Social Story™ by a teacher or TA professionally trained in Social Stories™ (the interventionist) for a period of approximately 4 weeks alongside their usual care which is likely to vary between schools. The interventionist will deliver the Social Story™ at least 6 times in this 4 week period.

8.2 Care as usual

The children in the comparator arm will receive care as usual (CAU) only. CAU will vary between schools but is likely to include a range of classroom interventions built into a child's learning plan (e.g. picture exchange communication system). We will collect information as to what care has been received in both groups systematically at all time-points using a resource use case report form.

8.3 Intervention Delivery and Training

The Social Stories™ will be delivered by an educational professional (the interventionist) who is employed by each school allocated to the intervention arm. The educational professional may vary between the schools (such as a teacher, TA, SENCO etc.).

The interventionist will be provided with a training manual and will attend a Social Stories™ training session providing information on their design and implementation. Parents of children randomised to the intervention arm will also be invited to attend these sessions to help with story construction though this is not a requirement for participation. During the training session the interventionist will construct a Social Story™ with input from the research team. The Social Story™ training involves working through a checklist of criteria to ensure the Social Story™ is fit for purpose. As a fidelity measure we will take a copy of each Social Story™ from these sessions and will assess them against the fidelity checklist. The purpose of this is to analyse the degree to which each story conforms to established criteria and allows for sensitivity analysis of outcome data.

8.4 Modifications or Variations in Delivery

The delivery of Social Stories™ may require modifications to account for differences in the children's demographic characteristics.

8.4.1. Presence of Comorbid Mental Health Problems

The proposed research will not exclude explicitly on the basis of comorbidities. However, there may be occasions when the teacher/TA or parent/guardian feels that a comorbid mental health condition may be made worse through trial participation. In these instances the child will be withdrawn from receiving the intervention but we will continue to collect data from the associated teachers and parents of these children. Those with comorbidities who are able to continue in the trial will receive the Social Stories™ or usual care as planned. If the child/young person has a care coordinator, wherever possible we will liaise with them about any specific needs or symptoms that we should consider and/or monitor throughout the intervention delivery.

8.4.2. Presence of Intellectual or Developmental Disabilities, Behavioural or Attention Problems

Some intellectual and developmental disabilities may mean we have to adapt intervention delivery. Where this is likely (e.g. children with ADHD), intervention delivery will be adapted to help the child. For example, this may involve more frequent breaks, or to have a trusted adult or other things present (e.g. a favourite toy) to comfort the child.

9. Data Collection

The main data collection time points are baseline, 6 weeks post-randomisation and 6 months post-randomisation. Baseline data collection will be completed by a trained research assistant, after informed consent has been given, at a convenient location for each participant. We will collect baseline measures from parents/guardians and associated teachers/TAs and demographic information from interventionists. The specific measures to be completed by these participants are outlined in Section 4.

For parents/guardians we recommend that they set aside 90 minutes for the baseline appointment to allow time for breaks and potential help completing the CRFs. For the follow-up appointments at 6 weeks and 6 months, we recommend that parents/guardians set aside 60 minutes. For the baseline associated teacher CRFs we ask that they set aside 60 minutes for the baseline appointment to also allow for setting the goal for the child, and 30 minutes for the follow-up appointments. The interventionist CRFs should take approximately 15 minutes to complete at each of the time points.

Research assistants will contact parents/guardians (via letter, email and/or phone) to discuss the method they would like to complete follow-up data collection (approximately 2 weeks before follow-up is due). Teachers/TAs and interventionists will be sent follow-up CRFs approximately one week before they are due for them to complete. This will be administered via post using and they will be provided with stamped addressed envelopes to return completed CRFs. In cases where CRFs have not been returned a telephone follow-up will be carried out (approximately 2 weeks after follow-up is due). All measures are self-report and children, parents and teachers will be aware of the treatment allocation for the trial.

9.1 Modifications or Variations in Data Collection

Randomisation will occur after consent has been obtained and baseline measures collected from parents and education professionals. If baseline data collection has been completed but term dates, school holidays, or school organisation delays randomisation (i.e. start of the intervention), and where this delay is significant (i.e. over the summer holidays), we will recollect baseline measures to ensure the data are up to date.

10. Blinding

The main trial statistician will be blind to group allocation at each phase of the trial. The DMEC will have access to the unblinded data at their request during the trial, this data will be prepared by the data management team in the CTU, aided by another CTU statistician when required.

Research assistants collecting outcome data will be blinded to the trial allocation. Instances of unblinding will be recorded using a bespoke unblinding form (which will include information on who was unblinded, the source of unblinding, and the reason for unblinding).

11. Withdrawal Criteria

Withdrawal can occur at any point during the study at the request of the participants or schools.

Where a participant (parent/guardian, child, teacher or interventionist) indicates that they wish to withdraw from the study, withdrawal will be clarified as to whether the withdrawal is from the intervention, from follow-up or from all aspects of the study. Where withdrawal is only from the intervention then follow-up data will continue to be collected.

Where a parent wishes to withdraw from the study, withdrawal will be clarified as to whether they wish their child to withdraw or if they themselves wish to withdraw (i.e. stop completing outcome measures). Where withdrawal is only for the participating parent, the child may continue to take part in all other aspects of the trial.

Where an interventionist wishes to withdraw, withdrawal will be clarified as whether the school wishes to withdraw or they themselves wish to withdraw. Where withdrawal is only for the interventionist, attempts will be made to replace them for the intervention period. Where a replacement interventionist cannot be recruited, the study team will discuss the implications of this with affected participant(s) to establish if they wish to continue with the study.

Where an associated teacher withdraws consent (or leaves the school without informing the research team) the research team will work with the school to identify another teacher who is willing to consent to participate in the trial. Where a replacement teacher cannot be recruited, the study team will discuss the implications of this with affected participant(s) to establish if they wish to continue with the study.

Where a school indicates that they wish to withdraw from the study this will result in the full withdarawl of all participant(s), teachers and interventionists at this school. No further data will be collected.

Data will be retained for all participants up to the date of withdrawal, unless they specifically request for their data to be removed. We will provide an opportunity for all those who withdraw or indeed who choose not to give informed consent to have a chance to explain why they have decided to not continue participation.

12. Process Evaluation

The process evaluation will involve a number of elements which will include an interventionist questionnaire, interviews and intervention fidelity assessment. The work carried out as part of the process evaluation will lead to two outputs. The first is an exemplar of the Social Story™ writing and delivery processes with at least one consenting family that leads to a CD/DVD to be made available for training. All participants will be fully informed and consented. The second is the creation of FAQ document detailing common problems or barriers faced by the interventionists and/or parents, identifying any elements of good practice. Both of these outputs will be freely available on the research team's website (www.comic.org.uk).

12.1 Interventionist Questionniare

All interventionist teachers and TAs will be asked to complete a questionnaire at 6 weeks and 6 months post-randomisation to identify barriers to implementation, to assess whether they continue to use Social Stories™ and, if so, whether any modifications have made.

12.2 Qualitative Study

Semi-structured interviews will be undertaken with 10-20 participants to explore the challenges and barriers to training and implementation of the intervention and, to understand how willing school staff were to run the intervention independently. These participants will be purposively selected from the cohort of trainers, Interventionists, Associated Teachers, and local authority representatives who have been involved in the trial. Additionally, parents who attended the training will also be invited to take part in the interviews. Purposive sampling will ensure maximum variation across the sample with regards to age, gender, time in profession, and experience with ASD. The proposed sample of interviewees is likely to achieve data saturation whereby similar themes emerge (Connor *et al.*, 2016; Schaffalitzky *et al*., 2011). A flexible interview schedule will be developed. Topic guides will be designed using data from the qualitative interviews carried out during the feasibility trial.

All interviews will be recorded with permission and recordings will be transcribed verbatim by approved transcribers and anonymised. Data will be transferred using secure, password-protected and encrypted methods in accordance with the Data Protection Policy for the Trust. A second researcher will check a sample of data transcripts against the audio recordings for accuracy, and will interrogate the validity of the coding against the raw data. NVivo software (or other appropriate software) will be used to structure and explore the interview data.

Following transcription, the interview material will be organised according to analytical headings using a constant comparison approach (Strauss & Corbin, 1998). To introduce transparency and a systematic approach we will engage in: detailed familiarisation; identification and indexing of key themes; contextualising these themes in relation to the broader dataset; and interpreting them with a focus on addressing the implementation of Social Stories™.

12.3 Fidelity

We will develop a protocol for ensuring and monitoring intervention fidelity and sustainability. This will be composed of the following mechanisms:

1. A training manual about Social Stories™ and their delivery.
2. The training manual will be used to inform a programme of training.
3. The content of the Social Stories™ will be monitored by fidelity checklists before intervention delivery and 6 weeks post randomisation to make sure they meet the criteria for a Social Story™.
4. During the pilot phase of the study, all Social Story™ writing sessions will be audio recorded (with consent). These audio recordings will be assessed against the process elements of the fidelity checklist.

12.4 Goal-based Observations

At baseline the Associated Teacher sets a behavioural goal for the participating child (with assistance from the parent/guardian, where possible). The Associated Teacher will rate how close the child is to meeting this particular goal at that time using our bespoke goal-based measure. At the 6 week and 6 month follow-up they will use the bespoke goal-based measure to rate how close the child is to meeting the goal at these follow-up time points. To validate this measure, at the 6 week and 6 month follow-up data collection points, 20% of the children will be observed in a classroom setting by a member of the research team. The researcher will be blinded to intervention allocation and will complete the same goal-based measure as the Associated Teacher. Consent to these observations is optional and participants will be randomly selected from those who have opted in.

We will take a pragmatic approach to the observations; some behavioural goals are focused on behaviour at playtime, and the behaviour in question would in all likelihood not display in the classroom. In these cases we will try to arrange to observe the child in a playtime setting. Similarly, in some cases the goals relate to behaviour that is not easily observable or able to be observed, in which case we will omit the observation of this participant. For example, it is relatively common for children with ASD to have issues around toileting. In some cases these types of issues may be the focus of the behavioural goal, however, it would not be appropriate for the researcher to carry out this observation. In these cases we will omit the observation of this participant

13. Economic Evaluation

The economic evaluation will consist of a cost-effectiveness analysis from an NHS, PSS and Education sector perspective. We will combine the cost of the intervention with any treatment benefit to calculate the incremental cost-effectiveness ratio. We will record the costs of delivering the treatment, including training costs. We will also collect data from the participant's associated parent about their resource use, such as visits to their GP and visits to other health and other social care providers and data from the associated teacher/TA about service use in school. These will be costed as outlined in Section 16.5. A secondary analysis will be conducted from a societal perspective. We will collect data on the carer costs using a resource use questionnaire as piloted in the feasibility study. These will include cost of productivity losses due to time spent caring for the child and out-of-pocket expenditures, such as travel costs.

14. Safety

14.1 Assessment and Management of Risk

We do not anticipate that trial participants will be subject to any substantial risks during this study. There is a potential however, due to the nature of ASD, for the participants to experience some distress associated with the novel social situation associated with introducing the intervention. They will follow usual school safety policies so as to avoid any harm. Staff members involved will receive training in autism awareness as part of the Social Stories™ training.

The intervention may intrude on some children's existing routines - this might cause distress for some children with ASD. The design of this study ensures that the intervention will take place within the school day i.e. as part of their existing scheduled activities, minimising this potential disruption.

14.2 Adverse Events

Possible harm as a result of the study is expected to be minimal but will be monitored according the York CTU Standard Operating Procedures (SOPs).

An adverse event (AE) related to participation in this study would be include emotional distress or social anxiety that could lead to behaviours such as:

- destruction of property (children may throw furniture or break other items),
- verbal abuse,
- physical violence (children with ASD may express frustration/sadness/anxiety through hitting/biting/aggression),
- running away to escape the situation.

All AEs will be assessed for seriousness, and will be recorded as a Serious Adverse Event (SAE) if it;

- results in death,
- is life-threatening,
- requires hospitalisation or prolongation of existing inpatients hospitalisation,
- results in persistent or significant disability or incapacity.

14.3 Collecting, Recording and Reporting of Adverse Events

Teachers and parents will be asked if they believe there have been any untoward events (above the child's usual behaviour) at 6 week post-randomisation follow-up.

AEs that are considered related to the participation in this study and all SAEs will be reported to the Chief Investigator (CI). SAEs considered related (to the intervention) and unexpected will be reported to the Sponsor, DMEC and TSC within 15 working days of the CTU being informed of the event. The TSC and DMEC will review all AEs at the next scheduled meeting.

As the trial exposes children with autism to a novel social situation (see Section 15.1) the DMEC will review the data at the end of the pilot and throughout the trial for safety. If there is evidence of harm due to the interventions or measures the DMEC will advise the TSC with a possible recommendation to stop the trial.

15. Statistics and Data Analysis

15.1 Sample size

The primary outcome is the SRS-2 questionnaire completed by the teacher at 6 months. Within the pilot data, outcomes were measured at 6 and 16 weeks. The correlation between baseline and 6 weeks (r=0.67, 95% CI 0.44 to 0.80) was lower than that at 16 weeks (r=0.83, 95% CI 0.68 to 0.91) for the pilot data. To be conservative we have chosen the lower 95% confidence limit for the lowest correlation between baseline and follow-up that we observed within our pilot data (r=0.44). A difference of 3 and standard deviation of 7 equates to an effect size of 0.43. Assuming 90% power we would require 230 (115 per group) after adjusting for the design effect (average cluster size 1.35 and ICC 0.34), correlation between baseline and 6 weeks from the feasibility study (0.44) and adjusting for 25% attrition a total sample size of 278 will be required. In addition, 278 parents/guardians, 278 associated teachers, and 139 interventionists will be recruited to the study as they will be needed to complete study specific questionnaires, and in the case of the interventionist, deliver the Social Stories™ intervention to the participating child.

15.2 Statistical analysis

Full analyses will be detailed in a statistical analysis plan (SAP), which will be finalised prior to the end of data collection. Analyses will be conducted using 2-sided significance tests at the 5% significance level (unless otherwise stated in the SAP). Baseline characteristics will be presented by trial arm. All trial outcomes will be reported descriptively by trial arm at all time points at which they were collected. Continuous baseline and outcome data will be summarised as means, standard deviations, medians and ranges, whereas categorical data will be summarised as frequencies and percentages.

As this is a pragmatic cluster RCT, data will be analysed and reported according to both RCT and cluster RCT CONSORT guidelines (Schulz, Altman, & Moher, 2010; Campbell, Piaggio, Elbourne & Altman, 2012). We will use ITT analysis for all outcome measures, that is those who withdraw from the treatment but complete outcome measures will be included in the analyses. This is the most appropriate form of analysis for a pragmatic trial as it maximises the external validity of the data despite the danger of dilution bias (Torgerson & Torgerson, 2008). Hence we can evaluate the evidence that the intervention has an effect on the social competence and perceived social isolation of children with ASD within a school setting.

The primary analysis will compare teacher reported SRS-2 score measured at 6 months between the randomisation groups using a generalised linear mixed model incorporating SRS-2 score collected at six weeks, adjusting as fixed effects for baseline characteristics (e.g. age of the child, sex of the child, etc), baseline SRS-2 score, stratification factors (i.e. the SEN status of the child's school and the number of recruited children in the child's school i.e. >5 vs ≤5), randomisation group, and school as a random effect. The model will account for the correlation of scores within pupil over time by means of an appropriate covariance structure. Intervention effects in the form of an adjusted mean difference will be presented with an associated 95% CI and p-value for both time points (six weeks and 6 months).

The secondary outcomes will be analysed in a similar manner as the primary outcome, with the baseline secondary outcome measure substituted for the baseline primary outcome measure. The summary of AEs and SAEs experienced by the students will be reported by treatment group.

15.3 Subgroup analysis

A subgroup analysis will be performed to explore the potential effect of the associated teacher's preference on the outcome. This will be for the primary outcome only and will be carried out by including an interaction term between the associated teacher's preference and randomisation group in the primary analysis model.

15.4 Missing or spurious data

We will assess the impact of missing data on the study results. Case and item missing data will be examined and multiple imputation methods may be used to reduce bias due to any missing responses in the analyses. Where appropriate, modelling methods that generate robust standard errors in the presence of missing data will be considered.

15.5 Fidelity Analysis

The fidelity evaluation will examine the extent to which the components of the intervention (Social Stories™) are delivered as planned, and the accommodations required by the host service/system to ensure this. Interventionists' adherence to core components will be assessed via researcher completed fidelity checklists of each Social Story™ after initial writing and at 6 weeks. This will correspond with the components set out in the respective manual.

15.6 Economic Analysis

The economic analysis will be conducted from an NHS, PSS and education sector perspective. The economic evaluation will take the form of a within-trial cost-effectiveness analysis that will determine the incremental cost per unit of outcome effectiveness measure for Social Stories™ compared with care as usual in children with autism. Health outcomes will be measured in terms of quality-adjusted life-years (QALYs) using the EQ-5D-Y (proxy version) as a health descriptor measure [the preferred instrument in the NICE reference case]. The domains of the EQ-5D-Y proxy will then be valued using UK population tariff to provide utility scores at multiple time points. QALYs will be estimated using time weighted averages of the utility scores measured at the beginning and end of each quarterly interval in the study time horizon.

The cost of the Social Stories™ intervention will be calculated using a bottom-up estimation of the time spent by professionals delivering the intervention, the cost of training and other resources used. Unit costs of health service use will be obtained from the UK national database of reference

costs. The cost of social services will be calculated from the Unit Costs of Health and Social Care, produced by the Personal Social Services Research Unit, and the cost of other professional support will be estimated from relevant salary scales and published reports/ literature.

A secondary evaluation will be conducted using a societal perspective. This will take account of the use of health services, education services and also the costs of productivity loss and out-of-pocket expenditures cost for parents, and voluntary services over the study period.

16. Data Quality and Handling

16.1 Data quality assurance

All measures are self-reported and will form the basis of all source data during this trial. Data collected as part of this research includes questionnaires and qualitative data from interviews. Data will be collected through designed questionnaires on paper. These paper forms will then be scanned at York CTU and the data stored in a database where they are checked against the hard copy of the questionnaire. Data is error checked and then validation checks are run against the database. Discrepancies identified during validation which require resolution are communicated to the relevant person who is in a position to obtain the information required to rectify the discrepancy.

Every attempt will be made to ensure the data is accurate, complete and reliable.

- If data are found to be missing from participant completed questionnaires, participants will be contacted by an RA in an attempt to collect the data.
- Validation reports will be run regularly by York CTU to check the study data for completeness, accuracy and consistency. Discrepancies will be generated and managed to resolution.
- Participants (parents/guardians, teachers, TAs, associated teachers, interventionists) will be contacted by phone (approximately two weeks after follow-up is due) asking them to complete follow-up CRFs.
- All interviews will be transcribed verbatim by approved transcribers. A second researcher will check a sample of data transcripts against the audio recordings, for accuracy, and will interrogate the validity of the coding against the raw data.

16.2 Data handling, storage and record keeping

Trial data will be extracted from source documents and entered onto the York CTU's in-house data management system.

Identifiable consenting participant details will be collected and entered on the database (on a secure password-protected server located at the University of York) but access to these personal details will be restricted to delegated users only and will be for the purposes of assisting in follow-ups during the study. All information collected during the course of the study will be kept strictly confidential. All identifiable participant data will be coded, pseudonymised by participant number in all manual and electronic files and no participant identifiable data will be transferred from the database to the statistician. Output for analysis will be generated in a format, and at intervals, to be agreed between York CTU and the CI. Data will be stored on University and NHS computers; these will all be password-protected. Data from qualitative interviews will be transferred onto the secure server as soon as possible and data removed from the portable recording device as soon as possible and stored on NHS computers.

All data will be collected and retained in accordance with the General Data Protection Regulation (May 2018) and York CTU SOPs. Copies of consent forms will be sent to the CTU for monitoring purposes. The study consent form will include optional statements affirming agreement with sharing anonymised data and affirming agreement to being contacted about future research.

The sponsor will permit monitoring and audits by the relevant authorities, including the HRA. The Chief Investigator will also allow monitoring and audits by these bodies and the sponsor, providing direct access to source data and documents, including the database. The CTU data management system incorporates quality control to validate study data.

16.3 Archiving

Study documentation and data will be archived at a suitable time following database lock. All essential study documents will be retained as part of the trial master file. All documentation and study data will be stored securely by the University of York on behalf of the Leeds and York Partnership NHS Foundation Trust for ten years after notification of study completion.

17. Monitoring, Audit and Inspection

Trial monitoring procedures and site monitoring will be undertaken at a level appropriate to a risk assessment performed by the Sponsor and the CTU according to CTU SOPs, and significant findings will be presented to the appropriate oversight committee.

Three committees will be established to govern the conduct of this study:

- A Trial Steering Committee (TSC).
- An Independent Data Monitoring and Ethics Committee (DMEC).
- A Trial Management Group (TMG).

These committees will function in accordance with York CTU SOPs. The TSC will consist of an independent chair, an independent subject specialist, an independent clinical academic, an independent statistician and a Patient and Public Involvement (PPI) representative. The DMEC will consist of an independent chair, an independent statistician, and another independent member experienced in research with children and families. The TSC and DMEC will meet approximately every 6 months from the start of the trial. The TMG will comprise the co-applicants, members of the trial team (including the data manager), PPI representatives, and the two trial managers. Meeting attendance of the co-applicants and trial team will depend on the agenda and relevance to their role.

18. Definition of End of Study

End of study will be defined as the date at which the last participant has completed the study processes.

19. Ethical Review

The proposed study will be conducted in accordance with ICH Good Clinical Practice guidelines. As the study is led from England, an application for NHS ethical approval in England will be made

and we will also apply to the Health Research Authority (HRA) for governance approval. Local R&D will confirm the capacity and capability of centres to participate.

20. Financial and Competing Interests

As part of the feasibility research prior to this grant, a treatment manual was developed which has been published by Jessica Kingsley Publishers.

One of the co-applicants is a named author on this and has given a written commitment to use any Royalties from sale of the manual (thought to be £0.50 per copy sold) towards purchasing copies of the guide to give to families in the research as free copies for their use.

21. Indemnity

To meet the potential legal liability for harm to participants arising from the design, conduct and management of the research, NHS employees will be covered by NHS indemnity and university employees will be covered by their institution's insurance. Intervention sessions will be held on school premises, therefore trial participants and all education professionals involved will be covered by the school's indemnity insurance.

22. Complaint handling

The PIS will provide participants with contact details of the Sponsor in case of complaint.

23. Amendments

All amendments will be approved by the CI and all substantial amendments will be approved by the CI, the Sponsor and the TMG prior to submission for ethical approval. Amendment history will be tracked by adopting version control and by the use of an amendment log.

24. Post trial care

All children on the autism spectrum will continue to have individualised support plans (for example, an individual education plan (IEP), individual health care plan, my support plan (MSPs), education health care plans (EHCPs), individual learning plans (ILP's) or equivalent) and these will be tailored to the needs of each child through usual school/ local authority processes.

25. Public and Patient Involvement

We have a PPI representative on our Trial Steering Committee who is on the autism spectrum themselves, is research active and a member of the National Autistic Society.

As part of our continuing commitment to engaging with PPI representatives we plan to support them by organising a meeting with stakeholders to discuss the dissemination of the study findings and identify a strategy for further dissemination of the findings.

26. Dissemination

The research team has a strong track record of successful dissemination of work funded by the NIHR and other funding bodies. We will begin to consider our dissemination strategy at an early stage of the project. We will publish the results of each phase of our study in high profile mainstream and specialist science journals, such as the British Journal of Psychiatry, the Journal of Child Psychology and Psychiatry, Clinical Child Psychology and Psychiatry and Journal of Autism and Developmental Disorders.

Presentations of study findings will be taken to relevant research conferences, local research symposia and seminars for CAMHS, child health and educational professionals. In addition, the National Autistic Society and members of service user groups such as ASCEND will be consulted in the development of methods and dissemination which will be effective in reaching families of children with ASD. Additionally, we will produce a short summary of the results that can be distributed to all trial participants as well as relevant interest groups, including patient groups. We will publish findings on relevant websites such as the National Autistic Society, university and child mental health websites. Finally, we will aim to ensure coverage of our findings in the wider media by issuing a press release.

Towards the end of the trial, our PPI representatives will organise a meeting with stakeholders including parents and professionals working with young people with ASD to specifically discuss the dissemination of the study findings. We will hold a research dissemination event for national and local clinicians and policy makers. Depending on findings, we will make suggestions to NICE about treatment evidence.

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28. Protocol Amendment History

Amendment No.	Protocol version no.	Date	Author(s) of changes	Details of changes made
01	1.11	04.12.2019	Shirley-Anne Paul	1. There was an error with the protocol version number on the front cover; this has now been updated from 1.9 to 1.11. 2. We have upated section 5 (Study Design and Setting) so that participants in SEN schools who will move from Y6 to Y7 within the duration of the study can be recruited. 3. A procedure for recollecting baseline measures has been added in a new section (9.1 Modifications or Variations in Data Collection).