A primary school research study to establish whether Social Stories™ can improve social and emotional health in children with autism spectrum disorder

Submission date 08/04/2019	Recruitment status No longer recruiting	 Prospectively registered [X] Protocol
Registration date 23/04/2019	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 19/12/2024	Condition category Mental and Behavioural Disorders	Individual participant data

Plain English summary of protocol

Current plain English summary as of 04/07/2020: Background and study aims

Children with autistic spectrum disorder (ASD) have a higher prevalence of mental health problems than typically developing children, including anxiety and low mood, disruptive, and repetitive behaviours. 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). Social Stories[™] are purported to promote calmer classrooms with improved learning/better integration in special and mainstream education settings, and improved social behaviours. Using Social Stories[™], children with ASD have shown improvements across a range of behaviours including social interaction, decision making, reduced disruptive behaviours, tantrums and frustration. The aim of this study is to find out whether Social Stories[™] can improve social responsiveness in children with ASD in primary schools.

Who can participate?

Children aged 4-11 who attend a school in Yorkshire and Humber and who have a diagnosis of ASD and daily challenging behaviour

What does the study involve?

Parents and teachers complete questionnaires at three times: at the beginning of the study (baseline), 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. After the baseline questionnaires have been completed for all participants at the school, the school is randomly assigned to either the Social Stories[™] intervention or to the control arm (which is care as usual (CAU) by the school). Assignment is decided at random by a computer and children receive all other treatment or support as usual regardless of allocation. If the school gets allocated to the intervention, a teacher is trained to write and read a Social Story[™] to the participating child at least 6 times in 4 weeks. If the school is allocated to the control group, the school continues supplying the care they have been given. However, once all

the data has been collected from CAU schools (after the 6 month questionnaires have been completed) the Social Stories™ training and manual are offered to CAU schools and parents.

What are the possible benefits and risks of participating?

Using the Social Stories[™] may help the child with their behaviour. Participants are offered free workshops on the writing and use of Social Stories[™] either as part of the intervention group or as part of the control group after data collection is completed. As a thank you for taking part the families will also receive a £20 voucher. 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.

Where is the study run from? Primary schools across Yorkshire and Humber.

When is the study starting and how long is it expected to run for? July 2018 to May 2022

Who is funding the study? National Institute for Health Research (NIHR) (UK)

Who is the main contact? 1. Dr Jane Blackwell Jane.Blackwell2@nhs.net 2. Dr Kerry Bell Kerry.Bell@york.ac.uk 3. Dr Catarina Teige c.teige@nhs.net 4. Prof. Barry Wright Barry.Wright1@nhs.net

Previous plain English summary:

Background and study aims

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Where is the study run from? Child Oriented Mental health Intervention Centre (COMIC) (UK)

When is the study starting and how long is it expected to run for? July 2018 to December 2021

Who is funding the study? National Institute for Health Research (NIHR) (UK)

Who is the main contact? 1. Dr Catarina Teige c.teige@nhs.net 2. Prof. Barry Wright barry.wright1@nhs.net

Contact information

Type(s) Scientific

Contact name Dr Jane Blackwell

Contact details

COMIC research team IT centre Innovation Way Science Park Heslington United Kingdom YO10 5NP +44 (0)1904 294244 Jane.blackwell2@nhs.net

Type(s) Scientific

Contact name Prof Barry Wright

Contact details

COMIC research team IT centre Innovation Way Science Park Heslington United Kingdom YO10 5NP +44 (0)1904 294244 barry.wright1@nhs.net

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 40949

Study information

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

Acronym ASSSIST2

Study objectives

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

Hypothesis: The researchers hypothesise that Social Stories[™] delivered in a school setting (>=6 times in a 4 week period) compared with the school's standard care program will have a greater benefit to social and emotional health in children with autism spectrum disorder.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 03/09/2018, Department of Health Sciences' Research Governance Committee (HSRGC) (University of York, Heslington, York, YO10 5DD; +44 (0)1904 323253; stephen. holland@york.ac.uk), ref: HSRGC/2018/286/D

2. Approved 24/07/2019, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH; hra.approval@nhs. net; approvals@wales.nhs.uk), ref: 19/NE/0237

Study design

Randomized; Both; Design type: Treatment, Education or Self-Management, Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s) School

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Childhood autism

Interventions

The trial design is a cluster randomised controlled trial with an internal pilot comparing the Social Story[™] intervention with care as usual. Trial participants are 4-11-year-old primary school children with a diagnosis of an autism spectrum disorder. The planned sample size is 278 and the primary follow-up will be 6 months post randomisation.

Social Stories intervention

Participating children allocated to the intervention group will have a Social Story[™] delivered to them 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. The Social Stories[™] will be delivered by an educational professional (the interventionist) who is employed by each school allocated to the intervention arm. The interventionist will attend a

Social Stories[™] training session with our research team providing information on their design and implementation. The schools randomised to the intervention will also be provided with a Social Stories[™] training manual. 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.

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). The researchers will collect information as to what care has been received in both groups systematically at all timepoints using a resource use case report form. Once the last of the data has been collected from CAU schools (after 6 months), the training and manual described above will be offered to the parents and teachers who are interested.

The trial period is 42 months. The researchers collect data at baseline, 6 weeks after randomisation, and 6 months after randomisation for both treatment arms. There will be an internal pilot study which will run for 10 months to examine the feasibility of recruitment. The pilot period will run for 10 months, at which point the researchers expect to have recruited n=110 of which one third (n=44) will have reached the primary endpoint. Stop/Go criteria based on 100% of the recruitment target will be used to assess the feasibility of continuing the trial. There will be a nested economic evaluation, process evaluation, qualitative component and fidelity assessment.

Intervention Type

Behavioural

Primary outcome measure

Child social responsiveness measured using the Social Responsiveness Scale, Second Edition (SRS-2)

Secondary outcome measures

1. Challenging behaviours measured using a 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) at 6 months

2. Social and emotional health measured using Revised Children Anxiety and Depression Scale (RCADS) short form at 6 months

3. Cost-effectiveness of Social Stories™ measured using a bespoke resource use questionnaire at 6 months

4. Health-related quality of life measured using a bespoke health care resource use questionnaire and EQ-5D-Y proxy at 6 months

5. Parental stress levels measured using Parental Stress Index (PSI) short form at 6 months

6. Classroom attendance and out of area placements measured using a bespoke questionnaire to determine current school care/education plan interventions and support provided to the child in class at 6 months

7. Sustainability of Social Stories™ measured using a bespoke Social Stories™ sustainability questionnaire at 6 months

8. Treatment preference measured using a bespoke preference questionnaire prior to

randomisation at baseline

9. Session delivery measured using a bespoke Social Stories[™] session log capturing frequency, length and times; problems or adverse events in the context of delivery at 6 weeks

Overall study start date 03/07/2018

Completion date

31/05/2022

Eligibility

Key inclusion criteria

Aged 4-11 years
 Attends a school in Yorkshire and Humber
 Has a research diagnostic criteria diagnosis of ASD and daily challenging behaviour

Participant type(s) Patient

Age group Child

Lower age limit 4 Years

Upper age limit 11 Years

Sex Both

Target number of participants Planned Sample Size: 278; UK Sample Size: 278

Total final enrolment 249

Key exclusion criteria

The school has used Social Stories[™] for the child in the current or preceding school term
 The child or interventionist teacher has taken part in the ASSSIST feasibility study. The study will not exclude schools that have taken part

Date of first enrolment 01/10/2018

Date of final enrolment 31/05/2021

Locations

Countries of recruitment England

United Kingdom

Study participating centre West Specialist Inclusive Learning Centre 4 Town Street Pudsey United Kingdom LS28 6HL

Study participating centre Newlands Primary School Wakefield Road Normanton United Kingdom WF6 1BB

Study participating centre Castleton Primary School Green Lane Leeds United Kingdom LS12 1JZ

Study participating centre

Ashfield Primary School Ceston Lane Otley United Kingdom LS21 2DF

Study participating centre

Victoria Primary School Cartmel Road Keighley United Kingdom BD21 2RD

Study participating centre

Thornton Primary School

Thornton Road Bradford United Kingdom BD13 3NN

Study participating centre High Crags Primary Leadership Academy Crag Road Shipley United Kingdom BD18 2ES

Study participating centre

Lacewood Primary School Carr Head Lane Rotherham United Kingdom S63 8DA

Study participating centre Kirk Sandall Infants and Juniors Schools Queen Mary Crescent Doncaster United Kingdom DN3 1JT

Study participating centre Chiltern Primary School Hull Chiltern Street Hull United Kingdom HU3 3PL

Study participating centre St Wilfrid's Roman Catholic Primary School Monkgate York United Kingdom YO31 7PB

Study participating centre Embsay Church of England Primary School Pasture Road Skipton United Kingdom BD23 6RH

Study participating centre Oatlands Community Junior School Beechwood Grove Harrogate United Kingdom HG2 8QP

Study participating centre Mowbray School Masham Road Bedale United Kingdom DL8 2SD

Study participating centre Luttons Community Primary School West Lutton Malton United Kingdom YO17 8TF

Study participating centre Aspin Park Academy Wetherby Road Knaresborough United Kingdom HG5 8LQ

Study participating centre Roecliffe Church of England Primary School Roecliffe York United Kingdom YO51 9NB

Study participating centre Riverside Community Primary School Wetherby Road Tadcaster United Kingdom LS24 9JN

Study participating centre Thomas Hinderwell Primary Academy Seamer Road Scarborough United Kingdom YO12 4HF

Study participating centre Sutton in Craven CP School

Bridge Road Keighley United Kingdom BD20 7ES

Study participating centre Saint Mary's Catholic Primary Voluntary Academy Wellington Street Grimsby United Kingdom DN32 7JX

Study participating centre

St Augustine Webster Catholic Voluntary Academy Bailden Road Scunthorpe United Kingdom DN15 8BU

Study participating centre Signhills Infant Academy and Signhills Academy 33 Hardys Road Cleethorpes United Kingdom DN35 0DL

Study participating centre Lisle Marsden Church of England Primary Academy Lansdowne Avenue Grismby United Kingdom DN32 0DF

Study participating centre Castle Academy Station Road Conisbrough Doncaster United Kingdom DN12 3DB

Study participating centre Brinsworth Whitehill Primary School Howlett Dr Brinsworth United Kingdom S60 5HT

Study participating centre East Dene Primary Doncaster Rd Rotherham United Kingdom S65 2DF

Study participating centre

Scawsby Saltersgate Infant School

Windsor Walk Doncaster United Kingdom DN5 8NQ

Study participating centre Seamer and Irton Community Primary School Denison Avenue

Seamer Scarborough United Kingdom YO12 4QX

Study participating centre

Whitley and Eggborough Community Primary School Learning Lane Goole United Kingdom DN14 0WE

Study participating centre Friarage Community Primary School Friargate Scarborough United Kingdom YO11 1HS

Study participating centre Cockburn Haig Road Academy Haigh Road Rothwell Leeds United Kingdom LS26 0NQ

Study participating centre Manston St James Primary Academy Sandbed Lane Leeds United Kingdom LS15 8JH

Study participating centre Windmill Church of England Primary School Upper Batley Lane Batley United Kingdom WF17 0NP

Study participating centre Oxspring Primary School Sheffield Road Oxspring Sheffield United Kingdom S36 8YW

Study participating centre

Athelstan Primary School Richmond Park Way Sheffield United Kingdom S13 8HH

Study participating centre Wetwang Church of England Primary School 21 Pulham Lane Driffield United Kingdom YO25 9XT

Study participating centre Stokesley Primary Academy 5 Springfield Stokesley Middlesborough United Kingdom TS9 5EW Study participating centre Our Lady of Sorrows Catholic Voluntary Academy Mere Lane Armthorpe Doncaster United Kingdom DN3 2DB

Study participating centre St Martins C of E Primary School Holbeck Hill Scarborough United Kingdom YO11 3BW

Study participating centre Hunter's Bar Junior School 371 Sharrow Vale Sheffield United Kingdom S11 8ZG

Study participating centre Bishopthorpe Infants School Sim Balk Lane Bishopthorpe York United Kingdom YO23 2QQ

Study participating centre Southcoates Primary School Southcoates Lane Hull United Kingdom HU9 3TW

Study participating centre

Braeburn Primary and Nursery Academy

Eastfield Scarborough United Kingdom YO11 3LG

Study participating centre East Whitby Academy

Stainsacre Lane Whitby United Kingdom YO22 4HU

Study participating centre North Cave C of E Primary School Station Road North Cave Hull United Kingdom HU15 2LA

Study participating centre Pocklington Juniors

65 Kirkland Street Pocklington York United Kingdom YO42 2BX

Study participating centre Beverley Minster Primary School St Gile's Croft Beverley United Kingdom HU17 8LA

Study participating centre Cawthorne Primary School Taylor Hill Cawthorne Barnsley

United Kingdom S75 4HB

Study participating centre Queens Road Academy Queens Road Barnsley United Kingdom S71 1AR

Study participating centre Bay Primary School St Alan Road Bridlington United Kingdom YO16 7SZ

Study participating centre Brompton Community Primary School Station Road Brompton Northallerton United Kingdom DL6 2RE

Study participating centre Market Weighton Infant School Princess Road Market Weighton United Kingdom YO43 3EY

Study participating centre Colburn Community Primary School Colburn Lane Colburn United Kingdom DL9 4LS

Study participating centre Brandesburton Primary School

Main Street Brandesburton East Yorkshire United Kingdom YO25 9RG

Study participating centre Tees, Esk & Wear Valley NHS Foundation Trust York United Kingdom YO30 4XT

Study participating centre Humber Teaching NHS Foundation Trust Hull United Kingdom HU10 6ED

Study participating centre Bradford District Care NHS Foundation Trust Bradford United Kingdom BD18 3LD

Study participating centre Harrogate and District NHS Foundation Trust Harrogate United Kingdom HG2 7SX

Study participating centre Sheffield Children's NHS Foundation Trust Sheffield United Kingdom S10 2TH

Study participating centre

Thorpe Primary School

Dolphin Lane Thorpe Wakefield United Kingdom WF3 3DG

Study participating centre Glasshoughton Infant Academy Newfield Avenue Castleford United Kingdom WF10 4BH

Study participating centre

Shire Oak CE Primary School Wood Lane Headingley Leeds United Kingdom LS6 2DT

Study participating centre St. Joseph's Catholic Primary School Barleyfields Road Wetherby West Yorkshire United Kingdom LS22 6PR

Study participating centre The John Curwen Cooperative Primary Leeds Old Road Heckmondwike Kirklees United Kingdom WF16 9BB

Study participating centre Kirk Sandall Infants and Juniors Schools Queen Mary Crescent Kirk Sandall Doncaster United Kingdom DN3 1JT

Study participating centre Newman School East Bawtry Road Rotherham United Kingdom S60 3LX

Study participating centre Carterknowle Junior School Carterknowle Road Sheffield United Kingdom S7 2DY

Study participating centre Dobcroft Junior and Infant School Pingle Road Sheffield United Kingdom S7 2LN

Study participating centre St Marie's School a Catholic Voluntary Academy Fullwood Road Sheffield United Kingdom S10 3DQ

Study participating centre Hatfield Academy - Astrea Academy Trust Hatfield House Lane Sheffield United Kingdom S5 6HY **Study participating centre Pocklington C.E (VC) Infant School** Maxwell Road Pocklington York United Kingdom YO42 2HE

Study participating centre Ralph Butterfield Primary School Station Road Haxby York United Kingdom YO32 3LS

Study participating centre Burton Green Primary School Burton Green York United Kingdom YO30 6JE

Study participating centre Clifton Green Primary Water Lane York United Kingdom YO30 6JA

Study participating centre Pickering Community Junior School Middleton Road Pickering United Kingdom YO18 8AJ

Study participating centre Kettlesing Ripley and Beckwithshaw Primary Schools Kettlesing Harrogate United Kingdom HG3 2LB

Study participating centre Kirk Fenton Parochial Primary School Main Street Church Fenton Tadcaster United Kingdom LS24 9RF

Study participating centre St Mary's Catholic Primary School Knaresborough Tentergate Road Knaresborough United Kingdom HG5 9BG

Study participating centre Grove Road Community Primary School Grove Road Harrogate United Kingdom HG3 3RW

Study participating centre Burton Leonard Church of England (VC) Primary School Burton Leonard Harrogate United Kingdom HG3 3RW

Study participating centre Holy Trinity Junior and Infant Schools Church Lane Ripon North Yorkshire United Kingdom HG4 2ES Study participating centre Woodlesford Primary School Church Street Leeds United Kingdom LS26 8RD

Study participating centre Outwood Junior Academy Brumby Queensway Scunthorpe United Kingdom DN16 2HY

Study participating centre Woolley Wood Primary Chaucer Road Sheffield United Kingdom S5 9QN

Study participating centre Leeming RAF Community Primary School Gatenby North Allerton United Kingdom DL7 9NQ

Study participating centre St Oswald's CE Primary School Heslington Lane Fulford York United Kingdom YO10 4LX

Study participating centre Stamford Bridge Primary School 5-7 Church Road Stamford Bridge United Kingdom YO41 1BP

Study participating centre Myrtle Park Primary School Ash Terrace Bingley United Kingdom BD16 1HB

Study participating centre Crossflatts Primary School Morton Lane Crossflatts Bingley United Kingdom BD16 2EP

Study participating centre St John Fisher Primary School Spring Water Avenue Sheffield United Kingdom S12 4HJ

Study participating centre Norton Community Primary School Grove Street Norton-on-Derwent Malton United Kingdom YO17 9BG

Study participating centre Sutton Park Primary School Marsdale Hull United Kingdom HU7 4AH

Study participating centre Acre Heads Primary School Welbourn Walk Norland Avenue Hull United Kingdom HU4 7ST

Study participating centre Knavesmire Primary School

Trafalgar St South Bank York United Kingdom YO23 1HY

Study participating centre Thrunscoe Primary and Nursery Academy Trinity Rd Cleethorpes United Kingdom DN35 8UL

Study participating centre North Ridge Community Tenter Balk Ln Adwick le Street Doncaster United Kingdom DN6 7EF

Study participating centre Spring Cottage Primary School Dressay Grove Hull United Kingdom HU8 9JH

Study participating centre

Greenfield Primary School

Cherry Tree St Hoyland Barnsley United Kingdom S74 9RG

Study participating centre Bradfield Dungworth Primary School Dungworth Green Sheffield United Kingdom S6 6HE

Study participating centre The Levett School Melton Road Spotbrough United Kingdom DN5 7SB

Study participating centre Penistone St Johns High Street

Penistone Barnsley United Kingdom S36 6FS

Study participating centre Green Lane Bradford United Kingdom BD8 8HT

Study participating centre Rowan School 4 Durvale Court Sheffield United Kingdom S17 3PT

Study participating centre Mosborough, Halfway Infants and Juniors New School Road Mosborough Sheffield United Kingdom S20 5ES

Study participating centre Kelford School Oakdale Road Kimberworth Rotherham United Kingdom S61 2NU

Study participating centre Meersbrook Bank Primary School Derbyshire Lane Meersbrook Sheffield United Kingdom S8 9EH

Study participating centre Stocksbridge Nursery Infant School Pot House Lane Stocksbridge Sheffield United Kingdom S36 1EJ

Study participating centre Alverton Community Primary School Mount Road

Northallerton United Kingdom DL6 1RB

Study participating centre Holgate Meadows and Heritage Park Norfolk Park Road Sheffield United Kingdom S2 2RU

Sponsor information

Organisation Leeds and York Partnership NHS Foundation Trust

Sponsor details c/o Alison Thompson Head of Research & Development Leeds England United Kingdom LS15 8ZB +44 (0)11385 52360 athompson11@nhs.net

Sponsor type Hospital/treatment centre

ROR https://ror.org/00n635c12

Funder(s)

Funder type Government

Funder Name NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/111/91

Results and Publications

Publication and dissemination plan

The research team has a strong track record of successful dissemination of work funded by the NIHR and other funding bodies. They will begin to consider their dissemination strategy at an early stage of the project. They will publish the results of each phase of the 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, and intend to publish main outcomes by 2021/2022.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository and will be included in the subsequent results publication.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/06/2020	15/06/2020	Yes	No
Abstract results			12/07/2022	No	No
<u>HRA research summary</u>			20/09/2023	No	No
<u>Results article</u>		31/08/2024	02/09/2024	Yes	No
<u>Results article</u>		17/12/2024	19/12/2024	Yes	No