

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/12/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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
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2. Dr Kerry Bell
Kerry.Bell@york.ac.uk
3. Dr Catarina Teige
c.teige@nhs.net
4. Prof. Barry Wright
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Previous plain English summary:

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.

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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
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IT centre
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United Kingdom
YO10 5NP
+44 (0)1904 294244
barry.wright1@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
40949

Study information

Scientific Title
Autism Spectrum Social Stories™ In Schools Trial 2 (ASSIST2)

Acronym
ASSIST2

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/05/2022

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

11 years

Sex

All

Total final enrolment

249

Key exclusion criteria

1. The school has used Social Stories™ for the child in the current or preceding school term
2. 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**

United Kingdom

England

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 Crag 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
Grimsby
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 Primary School
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

ROR

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly 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?
Results article		31/08/2024	02/09/2024	Yes	No
Results article		17/12/2024	19/12/2024	Yes	No
Protocol article	protocol	12/06/2020	15/06/2020	Yes	No
Abstract results			12/07/2022	No	No
HRA research summary			20/09/2023	No	No