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Autism Spectrum Social Stories In Schools Trial (ASSSIST)

Submission date
08/09/2011

Recruitment status
No longer recruiting

Registration date
09/09/2011

Overall study status
Completed

Last Edited
20/09/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The concept of social stories was created by Carol Gray in 2000. Simple, short stories, usually with the autistic child in the starring role, often with helpful photographs and illustrations and a theme relating to a particular social difficulty or life-skill problem. They break down the difficulty or problem into easily understood sequential stages, and include a) instructions on what are acceptable and preferred behaviours, and b) in-built demonstrations of what positive consequences might follow if they are enacted in real life. The child reads the story with parent /teacher and, with understanding and repetition, the preferred behaviour may be adopted, a new skill acquired, or even some complex anxieties alleviated. Social stories are already being used extensively in schools, but there has been little research to date on how best to structure and write one and how well they work. The aim of this study is to find out more.

Who can participate?
Children between the ages of 4-15 years diagnosed with ASD and with behavioural problems in school.

What does the study involve?
Stage 1: Developing a review of studies already carried out on social stories. This stage is called a systematic review (of existing evidence).
Stage 2: a) A discussion with children, teachers, and parents on their experiences with social stories, in which situations they have been used, and how successful they have been and in what way. It is hoped that this stage will reveal what the most common problem scenarios experienced by children with ASD are, which types of children benefit most from the stories, and which formats for the story work best.
Stage 2: b) The formation of an expert writing group whose role would be to formulate the ideal social story writing toolkit. Initial drafts would be passed between teachers, parents and professionals and refined until they are happy that the writing toolkit is clear, easy to follow and will result in a story which will be as effective as possible. Examples of particular templates for commonly encountered scenarios will be given. It is envisaged that although some of the templates devised as a result of our project might fit large groups of children, they will need to be individualised and bespoke, and clear guidelines will be incorporated as to how to do this. The team involved in developing the toolkit will attend a preliminary workshop led by Carol Gray, the

creator of the whole concept. Further training will be carried out in-house by the research team.
Stage 3: We will test whether the toolkit reduces challenging behaviour in a larger study. Before we can do this we need to do a small study (called a feasibility study) to test out the toolkit. Children aged 4-15 with a diagnosis of ASD who exhibit challenging behaviour will be eligible to take part in the study. We will test whether teachers, children and families like to use it, what they find helpful and unhelpful, how to measure changes and we will work out how a bigger study should work.
To do this, we will randomise (a bit like deciding by tossing a coin) some children to receive a social stories intervention with treatment as usual, whilst other children will receive and ordinary story with treatment as usual. Treatment as usual includes any other treatments except Social Stories (for example behavioural approaches, parenting support and social skills training). We will study 50 children in all (25 in each group). After the Social Story intervention, we will interview teachers, parents and children to find out their opinions on the study, such as the ease of use of the tool kit.
We will look at different ways of measuring the childrens behaviour. The systematic review will help us with this. This might include giving parents, teachers and children questionnaires such as the Strengths and Difficulties Questionnaire and the Developmental Behaviour Checklist. We will ask the child, family and teacher to set a clear goal for the Social Story and ask several people to rate it before and after the study.
We will also give parents a General Health Questionnaire before and after the study in order to measure any possible changes in their stress levels. We will also give parents and children questionnaires that ask what they think of the intervention and support received. We will not statistically analyse the differences in scores on any of the questionnaire measures because we will not have enough participants, but we will use them to work out how many children need to be in a larger study. We will look at which measures are the most informative and easy to use for the future large scale study.

What are the possible benefits and risks of participating?
We are mainly interested in finding out whether Social Stories improve childrens behaviour in their mainstream school setting, when targeted at improving social skills and social coping. Parents participating in the control group will be invited to free workshops at the end of the trial. Social Stories is an experimental intervention which is not routinely offered in the NHS.

Where is the study run from?
Participants will be recruited from 14 schools in the York area with the full support of the local authority. The focus groups and qualitative interviews will mainly take place in NHS centres associated with primary care. For example, in York, they will take place at Lime Trees child adolescent family unit.

When is the study starting and how long is it expected to run for?
This is a three year study, starting in October 2011 and finishing in September 2014

Who is funding the study?
NIHR Health Technology Assessment (HTA), UK

Who is the main contact?
Dr Barry Wright
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Contact information

Type(s)
Scientific

Contact name
Dr Barry Wright

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/169/07; Version 4.0 17/06/11

Study information

Scientific Title
Autism Spectrum Social Stories In Schools Trial: a feasibility randomised controlled trial

Acronym
ASSSIST

Study objectives
Social Stories are short stories which describe a social situation or social skill to help children and young people to understand the situation more easily and hence learn about socially expected behaviors and norms.

Current evidence suggests that Social Stories can be effective when tackling problem behaviours when they set out to explicitly teach social skills. It has been argued that exploring the meaning of behaviour from a childs perspective enables a better understanding and therefore more appropriately designed social stories. Until recently research exploring efficacy and outcome has been confined to case reports and case series. Case reports in children with autism have suggested improvements in social interactions, choice making in an educational setting, voice volume in class and mealtime skills.

The aim of our study is to build upon previous research to develop a manualised Social Stories intervention for use with Autism Spectrum Disorder (ASD) children in mainstream schools that has the effect of reducing challenging behaviour.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0916907
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/55208/PRO-09-169-07.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber, Leeds East, 06/09/2011, ref: 11/YH/0340

Study design
A three-phase study following the MRC framework for complex interventions. Phase II will assess and evaluate the intervention using a feasibility study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Autism Spectrum Disorder

Interventions
Participants in schools will be randomised to the intervention group will use Social Stories for between three and six months. The Social Stories will be delivered in a way that is informed by the pre clinical theory and phase 1 of this study using the most promising mode of delivery. This will include who designs the Social Story with parent and child, how this is achieved, and how and when the Social Story is delivered with the child. For example this could include a teacher, support assistant, special educational needs co-ordinator and /or a parent and they will receive support as part of the study from the clinical researchers. The precise from of this support will be designed using findings from the pre clinical theory and phase 1 of this study.

We will check the construction of the Social Stories paying particular attention to construction guidelines as laid down by the original Social Stories model. We will also explore any other parameters, including construction, content and delivery that have been found to be related to outcome as part of the systematic review and user and expert panels. As part of this, for example, we will measure goals of the intervention, intervention agents, intervention setting, timings of the intervention, length of the intervention and number of stories per child. We will also assess characteristics such as the number and distribution of pictures and photographs, and

the length and complexity of sentences, types of behaviours described and any allied interventions or support.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
At this point we have not chosen a main outcome measure as it is one of the purposes of the feasibility study to explore which outcome measures are most likely to be useful, which may include:

1. Developmental Behaviour Checklist (DBC; which includes ASD subscales and a disruptive subscale (parent and teacher)
2. Strengths and Difficulties Questionnaire (SDQ;which includes conduct, hyperactivity and prosocial subscales (parent, child, teacher)
3. Likert Scales for target behaviours designed and agreed by the focus groups/ expert panel (parent, child, teacher, and clinician). In this way we will develop a goal based outcomes scale and test its usefulness against the other instruments as part of our feasibility study
4. Generalisability will be assessed using questionnaires designed for each individual child that ask about the frequency of challenging behaviours for both the Social Story target behaviour and for other associated or related behaviours (e.g. if more positive behaviours in the class result in reduced destruction in the class are there also reductions seen in other settings, such as the dining hall, home etc). These will be parent and teacher based questionnaires used before and after the intervention.
5. General Health Questionnaire (parents)

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2011

Completion date
30/09/2014

Eligibility

Key inclusion criteria
In the feasibility RCT stage of the study,
1. Children will only be recruited between the ages of 4-15 years
2. Have a definite diagnosis of an ASD and have behavioural problems in school (as reported by parents and teachers)
3. We will prescreen children for challenging behaviour, using clinical interviews and measures informed by the systematic review, which may include the Strengths and Difficulties Questionnaire and the Developmental Behaviour Checklist

We have deliberately kept the age range broad in order to explore the acceptability of this intervention across age ranges and different settings (e.g. primary and secondary schools) and inform a fully powered trial.

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
This is a pragmatic trial which recognises the frequency and complexity of co-morbidities in children with autism spectrum disorders (ASD). We will therefore not exclude on the basis of comorbidity since the intervention would eventually be offered to this group if adopted more widely in the NHS. This will ensure that the research remains relevant to everyday clinical practice. This means for example that we will include children and young people with a learning disability, epilepsy, attentional problems, neurological disorders or syndromes (e.g. CHARGE syndrome, Fragile X syndrome etc).

We will exclude:
1. Any child from the study if they have used a Social Story within the last six months
2. Children and young people if they are likely to be moving school during the trial period, or if they develop behaviour or illness that warrants admission to a psychiatric unit (e.g. psychosis, serious self harm).

These exclusion criteria were informed by discussions with parents who had previously used Social Stories in a focus group prior to submitting the full application. Children will only be randomised into the trial if they exhibit challenging behaviours using the validated cut offs from the Strengths and Difficulties Questionnaire or the Developmental Behaviour Checklist.

Date of first enrolment
01/10/2011

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Limes Trees Child, Adolescent and Family Unit
York
United Kingdom
YO30 5RE

Sponsor information

Organisation
NHS North Yorkshire and York (UK)

Sponsor details
North and East Yorkshire Alliance Research & Development Unit
Learning and Research Centre
York Hospitals NHS Foundation Trust
York
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United Kingdom
YO31 8HE

Sponsor type
Hospital/treatment centre

Website
http://www.nyypct.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/07/2014		Yes	No
Results article	results	01/01/2016		Yes	No
Results article	results	11/08/2016		Yes	No