**Background:** Differences in the way autistic children experience the world can contribute to anxiety and stress. Carol Gray's Social Stories<sup>™</sup> are a highly personalised intervention to support children by providing social information about specific situations in the form of a short individually tailored story.

**Objectives:** This randomised controlled trial aimed to establish whether Social Stories<sup>™</sup> are clinically and cost-effective in improving social responsiveness, and social and emotional health in children on the autism spectrum in primary and special educational needs schools across Yorkshire and Humber.

**Design:** This was a multi-site pragmatic cluster randomised controlled trial comparing Social Stories™ with care and education as usual.

**Setting**: 87 schools across Yorkshire and the Humber took part.

Participants: 249 children from 87 schools were randomised (129 to receive Social Stories™ with care as usual and 120 to care as usual only). Recruitment completed in May 2021. Participants were children aged 4-11 years with a confirmed diagnosis of autism, alongside associated teachers, interventionists and caregivers. Participants were recruited via schools, NHS trusts, parent support groups, local authority professionals and from local publicity.

Intervention: The intervention consisted of a training session for educational professionals and caregivers that covered autism psychoeducation and the design and implementation of Social Stories™. Goals were set by the child's teacher in collaboration with caregivers around the child's need for social information. During the training session, interventionists constructed a Social Story™ including an individually contextualised goal. Following training, interventionists read the Social Story™ with the child at least 6 times over a 4-week period during the school day.

**Main outcome measure:** The primary outcome was the Social Responsiveness Scale-2 completed by teachers at 6 months post-randomisation, which measures social awareness, cognition, communication and behaviour. Follow-up data was collected from caregivers and educational professionals 6-weeks and 6-months post-randomisation within schools, participants' homes (or other public locations) or via telephone or video call. Blinding of participants was not possible.

**Results:** The primary analysis included all 249 randomised children. After 6 months, a reduction of 1.61 points was found on the Social Responsiveness Scale-2 in children on the autism spectrum in the intervention group

(95% CI -4.18 to 0.96, p=0.220). No statistically significant differences were found in overall symptoms of anxiety and/or depression, parental stress, or general health. Children in the intervention group met their individual goal more frequently than children who received usual care alone. Parents and educational professionals found the Social Stories<sup>™</sup> training and intervention beneficial and the intervention is likely to be cost-effective. Limitations include considerable disruptions during the COVID-19 pandemic.

**Conclusion:** Social Stories is frequently used in schools for children on the autism spectrum, and represents a low-cost, low-burden intervention. However, there is no clinically evident impact on social responsiveness, anxiety and/or depression, parental stress or general health. Benefits were observed for specific behavioural goals as assessed by the teacher and Social Stories<sup>TM</sup> may serve as a useful tool for facilitating dialogue between children and school staff to address specific behavioural challenges. Usage should be at the school's discretion.

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