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Investigating SOcial Competence and Isolation in children with Autism taking part in LEGO-based therapy clubs In School Environments (I-SOCIALISE): study protocol

Danielle Varley,[1] Barry Wright,[2,3] Cindy Cooper,[4] David Marshall,[2] Katie Biggs,[5] Shehzad Ali,[2,6] Tim Chater,[7] Elizabeth Coates,[7] Simon Gilbody,[2] Gina Gomez de la Cuesta,[8] Ellen Kingsley,[9] Ann Le Couteur,[10] Anne McKelvey,[11] Neil Shephard,[5] Dawn Teare[7]

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For numbered affiliations see end of article.

Correspondence to
Professor Barry Wright;
barry.wright1@nhs.net

ABSTRACT

Introduction Social skills training interventions for children with autism spectrum disorder (ASD) typically focus on a skills deficit model rather than building on existing skills or encouraging the child to seek their own solutions. LEGO-based therapy is a child-oriented intervention to help improve social interactional skills and reduce isolation. The therapy is designed for school-age children with ASD and uses group-based play in a school setting to encourage peer relationships and social learning. Despite the reported potential benefits of LEGO-based therapy in a prior randomised controlled trial (RCT) and its adoption by many schools, the evidence to support its effectiveness on the social and emotional well-being of children with ASD is limited and includes no assessment of cost-effectiveness.

Methods and analysis This multicentre, pragmatic, cluster RCT will randomise 240 participants (aged 7–15 years) with a clinical diagnosis of ASD to receive usual care or LEGO-based therapy with usual care. Cluster randomisation will be conducted on a school level, randomising each school as opposed to each individual child within a school. All prospective participants will be screened for eligibility before assenting to the study (with parents giving informed consent on behalf of their child). All participants will be followed up at 20 and 52 weeks after randomisation to assess for social, emotional and behavioural changes. The primary outcome measure is the social skills subscale of the Social Skills Improvement System completed by a teacher or teaching assistant associated with participating children at the 20-week follow-up time point.

Ethics and dissemination Ethics approval has been obtained via the University of York Research Ethics Committee. The results of the trial will be submitted for publication in a peer-reviewed journal and will be disseminated to participating families, education practitioners and the third sector including voluntary and community organisations.

Trial registration number ISRCTN64852382; Pre-results.

Strengths and limitations of this study

- Schools in the study will be cluster randomised to avoid treatment contamination.
- The study will address an under-researched area and will produce important research evidence to inform social development for children with autism spectrum disorder.
- Blinding of participants is not feasible due to the nature of the intervention.
- Steps were taken to minimise the impact of this including the blinding of study research assistants and trial statisticians.

INTRODUCTION

Autism spectrum disorder (ASD) is a lifelong neurodevelopmental disorder that affects between 1% and 1.5% of children in the UK and influences adult outcomes in areas such as mental health and social functioning (eg, independent living and friendships/intimate relationships).[1 2] Children with ASD are characterised by qualitative impairments in social communication, together with repetitive and often stereotyped behaviours and interests.[3 4] Children with ASD find it more difficult to intuitively understand societal norms and rules compared with their typically developing (TD) peers.[5] People with ASD are at higher risk of poor long-term outcomes including educational attainment, employment, social communication[6 7] and mental health.[8] It has become common practice in many western countries to include children with ASD in mainstream classrooms to support their social and academic development within an inclusive learning environment.[9 10] However, emerging evidence suggests such placements

can increase the risk of social isolation and rejection for some children with ASD.[11]

Peer relationships are an important aspect of social learning experience for most children.[12] Friendships require and help children to develop social, cognitive and language ability, as well as provide the child with a sense of belonging and self-worth.[13] Children with ASD engage socially in different ways compared with their TD peers and may struggle to initiate cooperative play, preferring structured self-directed activities with clear and explicit rules and limited emotional exchange.[14] These types of social behaviours may limit the child's experiences and opportunities to develop aspects of social and emotional competence.

Current social skills training interventions are limited by their focus on a skills deficit model, rather than building on a child's strengths. Additionally, the training often focuses on how children typically learn complex social rules but relies on the child's intuitive knowledge about how to apply the new skills across different social settings. One suggested finding is that although children with ASD can learn to demonstrate appropriate skills within the specific setting, applying the newly acquired skills in different social settings in their everyday life is often less successful.[6 15] A Cochrane review showed evidence that social skills training groups improved social competence but there were significant limitations in the published research, such as the different social skills measures, the narrow age ranges used across studies and the focus on a deficit model of ASD.[16] The authors suggested further research was needed to identify and evaluate specific interventions that can better inform reliable recommendations for practice and policy. One area of considerable interest is the design of child-friendly interventions that specifically make use of the strengths of children with ASD.

LEGO-based therapy[17] is a group-based social skills intervention that usually takes place in an educational setting. The intervention was designed for school-age children with ASD, using collaborative LEGO-based play to harness the child's own interests and so motivate shared learning with peers. This use of a shared focus has been recommended by international researchers.[17] LEGO is a predictable, systematic multilevel construction toy that provides intrinsically structured tasks that many children with ASD are highly motivated to complete.[18] LEGO-based therapy is designed to make social interactions interesting to the child with ASD, placing them in settings where they can learn to play co-operatively with a toy that they may enjoy. This naturalistic approach to treatment has previously been shown to improve the effectiveness of an intervention by increasing the likelihood that the new skills will be used beyond the therapy setting.[19] There is some preliminary evidence from the original authors that, at follow-up, social interactions in the playground were significantly improved.[17]

To date, only one randomised controlled trial (RCT) of 47 children with ASD (aged 6–11 years) has been conducted to investigate effects on the social and emotional well-being of children with ASD.[18] In this trial, LEGO-based therapy was compared with Social Use of Language Programme (a group-based social skills training intervention). These findings were then compared with a separately recruited control group comprising children matched on ASD symptoms, age and IQ, indicating that ASD-specific social difficulties reduced only in the LEGO-based therapy group. However, there are several limitations to this trial, such as small sample, lack of full random allocation, researcher organised therapy delivery and lack of treatment fidelity measures. An intention-to-treat analysis (ITT) was not employed as is best practice for RCTs.[20]

Therefore, despite the reported potential benefits of LEGO-based therapy and its increasing adoption by many schools in the UK, the evidence to support the effectiveness of this school-based intervention on the social and emotional well-being of children with ASD is limited. There has also been no evaluation of cost-effectiveness.

Rationale

A comprehensive set of public health guidelines were published by the National Institute for Health and Care Excellence (NICE),[21] which indicated that the social and emotional well-being of children is a critical determinant of their academic success and of their physical and mental health. Despite the benefits of a full inclusion policy, there is evidence that children with ASD may be at increased risk of rejection by their TD peers, social isolation and a number of associated negative impacts. However, the idiosyncrasy of the ASD symptom profile, alongside the difficulties many individuals with ASD have with generalising skills across settings, may make it especially hard for children with ASD to benefit from 'mainstream' social skills training groups.

NICE guidelines examining the evidence for interventions for children with ASD recommended specific social-communication interventions that employ play-based strategies (often with video-feedback) with parents, carers and teachers.[22] Although LEGO-based therapy is not specifically recommended, many of its components (eg, interactive play, techniques to expand communication, etc) are discussed as being potentially beneficial. There is a lack of evidence for the clinical and cost-effectiveness of LEGO-based therapy. However despite this, the intervention has been adopted by many schools across the UK. This cluster RCT aims to investigate the clinical and cost-effectiveness of LEGO-based therapy on the social and emotional well-being and perceived social isolation of children with ASD.

Trial design

The trial is a multisite, pragmatic, two-arm cluster RCT comparing LEGO-based therapy and usual support with a control group of usual support. The fidelity of the intervention will be systematically documented for the duration of the study using a standardised recording tool. A pragmatic approach was selected to maximise the

external validity of the trial and to allow us to examine the clinical effectiveness, sustainability and cost-effectiveness of the intervention.[20] There will be a 10-month internal pilot study, a nested qualitative component, an examination of treatment fidelity and an economic evaluation.

Participant recruitment and treatment will take place in schools. Baseline forms will be completed during visits which may take place in schools or participants' homes. Follow-up forms may be completed face-to-face or via post or secure online link sent via email.

OBJECTIVES

Primary objective

The primary objective of this trial is to examine the clinical effectiveness of LEGO-based therapy groups on the social and emotional competence (ie, perceived social skills as rated by educational staff) of children with ASD within the school setting, when compared with usual school-based support provided for children with ASD. This is measured using the social skills subscale of the Social Skills Improvement System (SSIS), completed by the associated teacher at 20 weeks. (NB: the SSIS is also completed as a secondary outcome by the associated teacher at baseline and 52 weeks and by the parent at baseline, 20 and 52 weeks).

Secondary objectives

The secondary objectives of this trial are to:

1. Examine the clinical effectiveness of LEGO-based therapy groups on the perceived social isolation of children with ASD within the school setting when compared with usual support provided. This is measured using the Multidimensional Scale of Perceived Social Support and the Asher Loneliness cale completed by the child at baseline, 20 and 52 weeks.
2. Examine the cost-effectiveness of LEGO-based therapy in terms of health-related quality of life and cost utility at 20 and 52 weeks. This is measured using the parent completed EQ-5D-Y proxy and bespoke resource use questionnaire, and the child completed Child Health Utility 9D (CHU-9D) at 20 and 52 weeks.
3. Determine if the impact of LEGO-based therapy is sustainable into the next academic year by comparing effectiveness on social and emotional competence (specifically perceived social skills) at 20 and 52 weeks. This is measured using the social skills subscale of the SSIS completed by the associated teacher at 20 and 52 weeks and a comparison between them.
4. Examine the acceptability of the intervention at follow-up points using a bespoke purpose designed questionnaire and telephone interviews. This is measured with the parent and interventionist completed bespoke acceptability questionnaire at 20 weeks (intervention group only).
5. Examine treatment fidelity through independent observation of treatment sessions across schools. This is measured using the fidelity checklist completed by the interventionist after each LEGO-based therapy session.
6. Examine the clinical effectiveness of LEGO-based therapy groups on the academic competence of children with ASD within the school setting, when compared with usual support provided for children with ASD. This is measured with the academic competence subscale of the SSIS completed by the associated teacher at baseline, 20 and 52 weeks.
7. Examine the emotional and behavioural symptoms in those receiving LEGO-based therapy compared with usual care. This is measured using the Strengths and Difficulties Questionnaire (SDQ) and the problem behaviours subscale of the SSIS completed by the parent and associated teacher at baseline, 20 and 52 weeks.
8. Examine the clinical effectiveness of LEGO-based therapy groups on assertion, social control, externalising and internalising of children with ASD within the school setting, when compared with usual support provided for children with ASD. This is measured using assertion and self-control items from the social skills subscale of the SSIS and externalising and internalising items from the problem behaviours subscale of the SSIS completed by the parent and associated teacher at 20 and 52 weeks.

METHODS AND ANALYSIS

Patient and public involvement

Patient and public involvement (PPI) is a central part of study design and management for this trial.

The original research proposal was developed in consultation with a representative from the National Autistic Society (NAS), a parent of a child with ASD and a young people PPI group. We recognise the need for independent qualitative data analysis, and will train a PPI representative to assist with the qualitative data analysis. The PPI representative will be reimbursed for their time, commensurate with current National Institute for Health Research (NIHR) INVOLVE guidelines.[23]

Non-compliance with Good Clinical Practice and the protocol will be monitored and recorded by the Investigating SOcial Competence and Isolation in children with Autism taking part in LEGO-based therapy clubs In School Environments (I-SOCIALISE) study team. All amendments will be approved by the Chief Investigator and all substantial amendments will be approved by the Chief Investigator, Sponsor and trial management group and will be submitted for approval by the ethics committee and the Health Research Authory (HRA) prior to implementation.

Eligibility criteria

A number of inclusion and exclusion criteria must be met before a child with ASD can be included in the trial. As I-SOCIALISE is a pragmatic RCT, few exclusion criteria will be applied. Both the school and the children in the

school must agree to participate before either can be included in the research.

Inclusion criteria

A school will be included if:

- It is a mainstream school in ethically approved participating localities.
- It has not used LEGO-based therapy with the child in the current or preceding school term.
- They have at least one child diagnosed with ASD (in line with child inclusion criteria below).

A child will be included if:

- They are aged between 7 and 15 years and attend a mainstream school in years 2–10.
- The child and parent/guardian have a sufficient understanding of English to be able to provide informed assent/consent and read the LEGO-based therapy instructions.
- They have an ASD clinical diagnosis from a qualified assessing clinician or team (based on best-practice guidance leading to the 10th revision of the International Statistical Classification of Diseases and Related Health Problems[4] or Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition[24] diagnosis as reported by the child's parent/guardian and in the child's school records).
- They score 15 or higher on the Social Communication Questionnaire (SCQ).
- They have the ability to follow and understand simple instructions.

Exclusion criteria

- The child has a physical impairment which would prevent them participating in the activities.

Recruitment

The study started in January 2017 with an aim to recruit 240 children across several localities in the North of England. The planned start date for enrolment of participants is September 2017, with an expected end date of April 2019. All follow-up data will then be collected by April 2020 shortly after which data analysis will commence.

Recruitment will involve the research team contacting mainstream primary and secondary schools. Information about the research will be sent to all mainstream schools located in the recruiting areas inviting them to participate with instructions on how to contact the research team if they would like further information, have any questions or would like to express interest. This will be followed up by a phone call to discuss the study with an appropriate staff member at the school. When an eligible child is identified by an education professional in their school, the researcher will provide the school with child, parent and education professional information sheets and ask the school staff to forward the appropriate sheets and forms to the child's parents. Once the parents contact the study team or the parent gives verbal permission for the school to pass on their contact details to the study team, a researcher will arrange to meet them to explain the study, answer questions and collect informed consent from them and assent from their child. If there are not enough eligible children with ASD in the school allocated to the intervention arm, other children (who are deemed suitable and/or may benefit from the therapy, eg, those with social isolation issues) and their parents/carers will be approached to join the LEGO-based therapy group. Limited identifiable data will be collected from these children (initials, sex and date of birth) in addition to assent/consent for being involved in the intervention group. We will obtain informed consent from all education professionals taking part in the study.

Randomisation

This two-arm trial will use a cluster randomisation process by participating school. The rationale for this design is due to the group-based nature of the therapeutic intervention and the need to control for contamination within schools. Randomisation will be conducted remotely by the Sheffield Clinical Trials Research Unit (CTRU). Randomisation will occur after consent and assent has been obtained from all interested and eligible families within the school. Schools and parents will be notified of their allocation via letter directly following randomisation. Additionally, schools will also receive an email regarding their allocation. We will stratify randomisation by school level (primary or secondary school) and by the number of consented children within the school (≤6 and >6 children).

Intervention: LEGO-based therapy and usual care.

Train the trainers' sessions with certified LEGO-based therapy trainers will take place in each locality led by the research team to familiarise trainers with the research intervention manual. School interventionists will be trained by local trainers or members of the research team using the research intervention manual (developed from the LEGO-based therapy manual,[17] specifically for this research).

Participating children allocated to the intervention arm will be invited to attend weekly groups lasting 45–60 min for a period of approximately 12 weeks. Groups will be run by a teacher or TA who has received LEGO-based therapy training specifically within the context of the research study.

Participating schools are able to run as many groups as is deemed appropriate as long as they have at least one eligible and consented child in each group. Each group will be made up of three children, although they can go ahead with fewer numbers if children are absent on the day of a planned session. Each group of children will work together with support from one trained member of school staff who is termed the 'interventionist'. In schools where there are not enough children with ASD to make a complete group, other children will be invited to join the group for its duration. These may include children who experience social difficulties whom teachers believe may benefit from the intervention. This is the current policy

of the local authorities and is the recommended method outlined by LeGoff *et al*.[17]

These children will also receive 'usual care', meaning that they will receive support as usual from their general practitioners (GPs), mental health and education professionals. Usual care is defined as normal practice for each school in addition to the usual support from the specialist teaching teams for autism in the area. This may include interventions such as the Picture Exchange Communication System, visual supports and timetables and Social Stories.

Should participants wish to discontinue the intervention and/or withdraw from the study, a member of the research team will complete a discontinuation form which records details of the event including reasons for withdrawal (if provided) and whether or not the participant has chosen to continue to provide data to the study.

Control: usual care only.

Participants allocated to 'usual care' receive only the usual care defined above. They will not receive the LEGO-based therapy intervention or any extra support services from the research team. All usual care provided in both groups will be recorded (see below). Control schools are asked not to run any LEGO-based therapy groups for the duration of the trial.

Should a participant in the control arm wish to withdraw from the study, the same process used for intervention participants will be employed.

Outcomes (primary and secondary)

The primary outcome measure for I-SOCIALISE is the social skills subscale of the SSIS,[25] completed by the associated teacher/teaching assistant (TA) (an education professional who knows the participant well but is not the interventionist teacher/TA) at 20 weeks post randomisation. It is widely used in national portfolio studies and has been shown to be sensitive to change resulting from interventions in children with ASD. The associated teacher/TA will be asked to complete the SSIS at baseline, 20 and 52 weeks after randomisation. The primary outcome is 20 weeks after randomisation. The 20-week follow-up point was chosen to be an approximation of the average expected duration of the intervention while allowing for slippage due to potential delay in training, school holidays and absences.

The secondary outcomes of the study are outlined by respondent below, including the problem behaviours and academic competence subscales of the SSIS. All measures will be collected at baseline, 20 weeks and 52 weeks after randomisation unless otherwise stated. The secondary end point is 52 weeks after randomisation.

Associated teacher/TA questionnaires

1. The SSIS,[25] (primary outcome measure).
2. The SDQ.[26]
3. Bespoke resource use questionnaires to capture the resource implications of a child's behaviour at school and as a way of recording care and interventions as usual received in both arms.
4. Custom designed questions (included in resource use form at 20 weeks) to assess any adverse events that may have been attributable to the intervention—*20 weeks only*.

Interventionist teacher/TA questionnaires

1. Demographic information will be collected from the interventionist teachers using a novel demographic information form and relating to training and experience—*baseline only*.
2. A bespoke resource use questionnaire to capture the resource implications of running the LEGO-based therapy sessions at school—*after each session*.
3. Custom designed questions (included in session resource use form) to assess any adverse events that may have been attributable to the intervention—*after each session*.
4. A fidelity checklist to complete after each LEGO-based therapy session based on the existing treatment manual[17]—*after each session*.

A bespoke questionnaire to assess acceptability of the intervention structured around the Theoretical Framework of Acceptability[27]—*20 weeks only*.

Child questionnaires

1. The Multidimensional Scale of Perceived Social Support.[28]
2. The Asher Loneliness Scale.[29]
3. CHU-9D.[30]

Parent questionnaires

1. The SCQ[31]—*baseline only*.
2. The SSIS.[25]
3. The SDQ.[26]
4. The EQ-5D-Y (3L proxy version).[32]
5. Bespoke resource use questionnaires to capture the healthcare and non-health resource implications attributable to the child's autism spectrum disorder.
6. Bespoke questionnaire to assess acceptability of the intervention. Structured around the Theoretical Framework of Acceptability[27]—*20 weeks only*.
7. Custom designed questions (included in resource use form at 20 weeks) to assess any adverse events that may have been attributable to the trial intervention or usual care interventions— *20 weeks only*.
8. Demographic information pertaining to the child and the parent will be collected. This will be done using a bespoke demographic information form—*baseline only*.

Blinding

Blinding of participants is not feasible due to the nature of the intervention. Steps have been taken to minimise the impact of this. Research assistants collecting outcome data will be blinded to the intervention being received. Instances of unblinding will be recorded using a bespoke case report form (CRF) (which will include information on who was unblinded, the source of unblinding and the reason for unblinding). All measures are self-report and children, parents and teachers will be aware of the treatment allocation for the trial.

The trial statisticians will remain blind throughout the duration of the study period, with both statisticians being blind to group allocation at each phase of the trial. The Data Monitoring Ethics Committee will have access to the unblinded data at their request during the trial, for example, if they are concerned of potential harm caused by the intervention; these data will be prepared by the data management team in the CTRU, aided by another CTRU statistician when required.

Data collection

Data will either be recorded in paper CRFs or online at the time of each participant contact. All CRFs will use anonymised participant ID codes to protect participant confidentiality. Initial CRFs completed at baseline will typically be completed face-to-face, with the option of postal completion. Follow-up CRFs can be completed at a face-to-face visit or via postal or online forms. The paper CRFs will be entered into Sheffield CTRU's in-house data management system, Prospect, which stores data in a PostgreSQL database on virtual servers hosted by Corporate Information and Computing Services. Original datasheets will be securely stored at each site according to the ethics committee's protocol. All data will be collected and retained in accordance with the Data Protection Act 2018, the General Data Protection Regulation and CTRU standard operating procedures.

Statistical analysis and sample size rationale

Primary and secondary outcomes analysis

The primary outcome will be the associated teacher-reported social skills subscale of the SSIS score measured at 20 weeks. This subscale is a summated score which we will treat as a continuous variable. All measures will be compared between the two intervention groups using a generalised linear mixed model to account for the clustering and the repeated measures. The following variables will be included as covariates: age, sex, baseline social skills subscale of the SSIS score, participant group (random effect) and school level. Stratification of two levels (≤6 and >6 eligible children) is employed to protect against imbalance in allocation which may arise if schools with large numbers of eligible children are recruited.[33] An unadjusted analysis (difference between group means and 95% CIs) will be reported alongside the adjusted analysis. The significance level with be set at 5% for testing the primary outcome.

The secondary outcome variables will also be treated as continuous variables and analysed (adjusting for baseline score, age, sex, school level (stratification variable), number of eligible children (stratification variable), participant group (stratification variable) and school (random effect)) using the generalised linear mixed model framework.

Per-protocol sensitivity analyses will be performed with compliance defined as attending six or more of the therapy sessions.

We anticipate some attrition so missing data may be an issue. Case and item missing data will be examined and multiple imputation methods will be used to reduce bias due to any missing responses in the analyses. Where appropriate, modelling methods that generate robust standard errors (SEs) in the presence of missing data will be considered.

Acceptability analysis

Acceptability of the intervention to children will be assessed by the number of sessions attended and data collected from the interventionist and parent, to minimise overburden of the participants at each session. A questionnaire has been designed to assess acceptability of the intervention to the parents and the interventionists at the 20-week time point. This is based around the Theoretical Framework of Acceptability.[27]

Qualitative analysis

A purposive sample of 20% of the interventionists (n=12) across school types (primary/secondary and sociodemographic variables) postintervention will be interviewed to gather their feedback on delivering LEGO-based therapy and perceived acceptability to children, parents and the school. The interviews will be undertaken by a member of the research team who will be unblinded to trial allocation. Normalisation Process Theory[34] will be used throughout the interviews to guide data collection and to frame the analysis to understand how easy it is to implement LEGO-based therapy into routine practice. All interviews will be recorded and transcribed verbatim. The framework analysis approach[35] will be used to structure and explore the interview data, and NVivo software will be used to support this process.

Fidelity analysis

The fidelity evaluation will examine the extent to which the components of the intervention (LEGO-based therapy) are delivered as planned, and the accommodations required by the host service/system to ensure this. School interventionists' adherence to core components of LEGO-based therapy will be assessed using standardised, weekly completed checklists developed by the research team to assess implementation fidelity. These checklists include indices for fidelity of intervention delivery, receipt and enactment (informed by the approach taken by, Borrelli *et al*[36]).

Seventy-two (10%) of the LEGO-based therapy sessions across the study will be video-recorded by members of the research team who are not collecting outcome data. Recordings will only be done with participants who have given informed consent.

To provide an assessment of fidelity of intervention delivery, the video sessions will be reviewed and rated using the fidelity checklist by one of the independent observers. Inter-rater reliability will be calculated for a subsample of sessions.

Economic analysis

Using a UK NHS and education 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 measure for LEGO-based therapy compared with usual support in children with ASD. Health outcomes will be measured in terms of quality-adjusted life years (QALYs) using EQ-5D-Y proxy as a health descriptor measure (the preferred instrument in the NICE reference case). The domains of EQ-5D-Y proxy (3L version) will then be valued using UK population tariff to provide utility scores at multiple time points. A secondary analysis will be conducted using the CHU-9D measure to estimate QALYs based on the UK population tariff.[30]

Resource use data will be collected using a bespoke questionnaire that will capture data on the following: (1) use of community health services, including appointments with GP, nurse, child development centre, walk-in-centre, social worker, family support worker, educational psychologist, educational welfare officer and school and college nurse; (2) mental health services, including psychiatrist, psychologist, Child and Adolescent Mental Health Services (CAMHS) therapist, mental health nurse, family therapist, GP counselling, school counsellor and any privately paid mental health services; (3) hospital visits, including outpatient visits, inpatient admissions, accidents and emergency visits and urgent care centre visits; (4) school-based interventions/support provided by teachers and (5) cost of the LEGO-based therapy sessions. Data on costs and outcomes will be analysed together using an incremental cost-effectiveness analysis which evaluates differences in costs and effects against a range of willingness-pay thresholds of the decision maker for a one unit gain in QALY.

Sample size calculation

The sample size calculation is based on a Cochrane review,[12] which reported on five studies that examined the effects of social skills groups on social competence. This context was selected as the best indicator of realistic clinical effectiveness on the basis that if the proposed intervention was to be viable it needs to be at least as effective as running a social skills group in school. Of the five studies included in this review, four were RCTs and reported standardised measures of social competence which could be synthesised through meta-analysis techniques. The weighted mean SD in social competence between group treatment and services as usual was 0.47 (95% CI 0.16 to 0.78). Reichow [16] argued that this average effect size of almost 0.5 SD corresponds to a clinically significant change, 'to put these gains in more concrete terms, if measuring everyday socials skills using the Vineland Adaptive Behaviour Scale,[37] for example, an average participant from these studies would increase their repertoire of social skills from 123 to 147 after participating in the social skills group which is a clinically significant increase'. Calculations using this standardised effect size of 0.47, 90% power and 5% two-sided significance results in a sample size of 97 participants groups per condition or 194 participants groups in total. Attrition rates varied between 0% and 16% for the studies included in the Cochrane review.[12] As such, a conservative estimate of 16% inflates the sample to a final size of 116 participants groups per condition or 232 in total. The research team has accounted for trainer/school effects and a cluster size of approximately four (two participants per therapy group and two therapy groups per school) (intraclass correlation coefficient (ICC)=0.01). This is based on the findings of the Autism Spectrum Social Stories™ in Schools Trial (ASSSIST) feasibility study conducted in one of the recruiting sites.[38] This figure was further inflated and rounded up to 120 participants groups per condition or 240 in total. We anticipate recruitment of 12 per month across all sites and have a retention rate of 84% at 20-week follow-up. The pilot period will run for 10 months, at which point we expect to have recruited n=120 of which one-third (n=40) will have reached the primary end point. Stop/Go criteria based on 75% of recruitment target (n=90) and 70% of the primary outcome measures (n=28) will be used to assess feasibility of continuing the trial.

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.

ETHICS AND DISSEMINATION

Ethics

Local authority or academy approval will be sought from each of the areas in which participants are to be recruited. Any changes to study documents will be reviewed and approved in line with HRA requirements and annual reports will be sent to the HRA. The trial has been extensively peer reviewed as part of the National Institute for Health Research Public Health Research funding process.

Dissemination

We will endeavour to publish the results of each phase of our study in high profile mainstream and specialist science peer-reviewed open access journals. 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 NAS and members of parent/carer groups such as Autism Spectrum Conditions—Enhancing Nurture and Development,[39] will be consulted in the development of methods and dissemination which will improve the likelihood of effectively sharing study findings with 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 NAS, 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.

DISCUSSION

This research aims to assess the clinical and cost-effectiveness of LEGO-based therapy groups in mainstream school settings while also assessing its sustainability, acceptability, fidelity and emotional and behavioural symptoms of participants.

The trial opened in September 2017 and will report findings in 2020.

Author affiliations
[1]COMIC, Leeds and York Partnership NHS Foundation Trust, York, UK
[2]Department of Health Sciences, University of York, York, UK
[3]Hull York Medical School, University of York, York, England
[4]ScHARR, University of Sheffield, Sheffield, UK
[5]Clinical Trials Research Unit, University of Sheffield, Sheffield, UK
[6]Department of Epidemiology and Biostatistics, Western University, London, Ontario, Canada
[7]School of Health and Related Research, University of Sheffield, Sheffield, UK
[8]Cambridgeshire Community Services NHS Trust, Cambridge, UK
[9]Leeds and York Partnership NHS Foundation Trust, York, UK
[10]Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
[11]City of York Council, York, UK

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Contributors DV, BDW, CC, DM, KB, SG, GGdlC, ALC, AM and MDT were responsible for the conception and design of the draft of the protocol. EK, TC, NS and EC were responsible for substantial alterations to the protocol and design of the study and the acquisition of the data. SA was responsible for the design and analysis of the health economic component of the trial. All authors made substantial contributions to the drafting, critical revision and final approval of the document.

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Competing interests The research team are aware that the LEGO name is a registered trademark and will follow their fair use policy in regard to the LEGO brand throughout the duration of the trial. Co-applicant Gina Gomez de la Cuesta coauthored the LEGO-based therapy manual 17 which will form the basis of the LEGO-based therapy delivered in the trial. The coauthors of the manual have given us full permission to use the manual without licence and to develop an abridged version. They have also stated their support for us in writing our own version, and will become coauthors on any future publications. Co-applicant Gomez has also agreed for the team to adapt the fidelity checklist used in her previous study. We have provisional agreement with Jessica Kingsley Publishers who have expressed interest in publishing the abridged manual. However, we are not tied to them as a publisher. There are no other financial and/or competing interests to declare.

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