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# An evaluation of LEGO-based therapy in school for children with autism

**Submission date**
31/07/2017

**Recruitment status**
No longer recruiting

**Registration date**
30/08/2017

**Overall study status**
Completed

**Last Edited**
10/09/2025

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Current plain English summary as of 11/02/2019:
Background and study aims
It is estimated that approximately 1.6% of people in the UK have autism spectrum disorder (ASD) which causes difficulties with social interaction, communication, behaviour, and interests. Such difficulties often cause problems in day to day life and often result in the child feeling socially isolated.
The most common treatment for this is social skills training but while these children may learn to demonstrate appropriate social skills within the setting of the intervention, applying these new skills to their everyday life is often unsuccessful. LEGO-based therapy is a new approach that is specifically designed to make social interactions interesting to the child with ASD so that they will not only learn the necessary skills but adopt them in their daily lives. The aim of this research is to examine whether LEGO-based therapy groups in schools has any impact on the social and emotional competence and perceived social isolation of children with ASD. The research also aims to look at any changes in the mental and more general health of the child resulting from LEGO-based therapy.

Who can participate?
Children aged seven to 15 who have an ASD diagnosis and schools located in Leeds, York or Sheffield.

What does the study involve?
The therapy is delivered by an assigned school teaching assistant within the child's school. Children are randomly allocated to one of two groups. Those in the first group attend a weekly LEGO-based therapy group once a week for 12 weeks. Those in the second group receive access to their usual care which includes support from their GPs, mental health and education professionals.
The Social Skills Improvement System (SSIS) is completed on behalf of each child (in both groups) by teachers and change in these scores will be the main consideration of this research. Participants also have their loneliness and quality of life are assessed 16 weeks after the beginning of the study and again in the next school year to see if LEGO-based therapy makes any difference compared to usual care and whether any differences last into the next school year.

What are the possible benefits and risks of participating?
The possible benefits of this therapy are that it was designed for school-age children with ASD as opposed to being an adapted form of a more generic social skills training intervention. Using collaborative LEGO®-based play the intention is to harness the child's own interests and so motivate learning and change a focus recommended by international researchers in this area. LEGO® is a predictable, systematic multi-level construction toy that provides intrinsically structured tasks that children with ASD are highly motivated to complete. LEGO®-based therapy is specifically designed to make social interactions interesting to the child with ASD so that they learn how to play co-operatively with a toy that they enjoy which in turn increases the likelihood that they can continue to use these skills in their daily functioning. This use of a naturalistic approach to treatment has previously been shown to improve the effectiveness of an intervention by increasing the likelihood that the newly acquired skills will be used beyond the therapy setting. There is some preliminary evidence from the original authors that at follow up social interactions in the school playground were significantly improved. There are no anticipated risks with participation. LEGO®-based therapy focuses on helping children gain positive social and situational strategies using intrinsically rewarding and varied types of collaborative LEGO®-based play, therefore is unlikely to cause participants direct harm. There is a potential however, due to the nature of ASD, for the participants to experience some distress associated with the novel social situation and the social roles the child is taking on during the therapy. As with all toys there is a risk of children injuring themselves or each other. To minimise these potential constraints, sessions will be closely supervised by familiar members of school staff (interventionists) with a high degree of experience of using play equipment with children within the school environment. They will follow usual school safety policies. Also, within the first session, and at the start of each subsequent session, the participants will be asked to follow some 'Brick Club rules'. These include procedures for dealing with disagreements, taking turns within the session and being helpful to other participants. The intervention may intrude on some children's existing routines - this might cause distress for some children with ASD. The design of this study ensures that the intervention will take place within the school day i.e. as part of their existing scheduled activities, minimising this potential disruption. There is also the risk that LEGO®-based therapy will not be effective leading to a misuse of time and resources in schools. However, given the extensive and growing interest in this therapy in the UK, this risk is counterbalanced by the likelihood that by not undertaking an evaluation at this time a treatment with limited evidence of clinical and cost- effectiveness will be rolled out nationally.

Where is the study run from?
This study is being run by the University of Sheffield and takes place in schools in Leeds, York, or Sheffield.

When is the study starting and how long is it expected to run for?
January 2017 to December 2020

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

Who is the main contact?
Ms Ellen Kingsley
e.kingsley@nhs.net

Previous plain English summary:
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National Institute for Health Research (UK)

Who is the main contact?
1. Ms Katie Biggs
c.e.biggs@sheffield.ac.uk
2. Ms Danielle Varley
danielle.varley@nhs.net

# Contact information

### Type(s)
Public

### Contact name
Ms Ellen Kingsley

### Contact details
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# Additional identifiers

### Protocol serial number
I-SOCIALISE protocol version 5

# Study information

## Scientific Title
Investigating SOcial Competence and Isolation in children with Autism taking part in LEGO®-based therapy clubs In School Environments

## Acronym
I-SOCIALISE

## Study objectives
The aim of this trial is to examine the clinical effectiveness of LEGO®-based therapy groups on the social and emotional competence (including perceived social skills, challenging behaviours and academic confidence) of children with ASD within a mainstream school setting, when compared with usual support provided for children with ASD.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
University of York Research Ethics Committee, 04/05/2017, ref: Wright1

## Primary study design
Interventional

## Study design
Randomized controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Autism

## Interventions
Participants are randomly allocated using a cluster randomisation process by participating school. The rationale for this design is due to the group based nature of the therapeutic intervention and to control for contamination within schools. Randomisation occurs after eligibility has been established, consent has been obtained and baseline measures collected from teachers/teaching assistants.

Intervention arm:
Participants receive LEGO-based therapy. LEGO®-based therapy is a social skills based therapy that is specifically designed to make social interactions interesting to a child with autism. Children allocated to the intervention attend a weekly LEGO®-based therapy group for 12 weeks. The primary follow-up point is 16 weeks after baseline measures are collected.
The secondary follow-up point is 52 weeks after baseline measures are collected.

Control arm:
Participants receive support as usual from their GPs, mental health and education professionals. Children allocated to the comparator arm will continue receiving support as usual for 12 weeks. The primary follow-up point is 16 weeks after baseline measures are collected. The secondary follow-up point is 52 weeks after baseline measures are collected.

The Social Skills Improvement System (SSIS) is completed on behalf of each child (in both groups) by teachers and change in these scores will be the main consideration of this research.

The Asher loneliness scale, and a number of quality of life questionnaires are also completed. For each child and changes in these are also be examined. All these measures are completed as soon as the child agrees to take part in the research, 16 weeks after this point and again in the next school year. This is done to see if LEGO-based therapy makes any difference compared to usual care and whether any differences last into the next school year. A small number of interviews with participants about the acceptability of the intervention are completed.

## Intervention Type
Other

## Primary outcome(s)
Social and emotional competence (including perceived social skills, challenging behaviours and academic confidence) is measured using the Social Skills Improvement System (SSIS) (completed by the teacher) at 16 weeks

Updated 04/05/2018: Measured at 20 weeks

## Key secondary outcome(s)
1. Perceived social isolation is measured using Multidimensional Scale of Perceived Social Support (8 items relating to support from friend) (completed by the child) at 16 and 52 weeks
2. Perceived social support from family, friends and significant others is measured using Asher Loneliness Scale (completed by the child) at 16 and 52 weeks
3. Health related quality of life is measured using Child Health Utility 9D scale at 16 and 52 weeks
4. Eligibility is measured using social communication questionnaire (completed by parents) at – The SCQ will be completed by parents as an eligibility check prior to baseline assessment.
5. Social and emotional competence (including perceived social skills, challenging behaviours and academic confidence) is measured using the Social Skills Improvement System (completed by parents) at 16 and 52 weeks
6. The child's emotional and behavioural difficulties, distress and social impairment is measured using the Strengths and Difficulties Questionnaire (completed by parents) at 16 and 52 weeks
7. Cost effectiveness is measured using a bespoke resource use questionnaire (completed by parents) at 16 and 52 weeks
8. Safety is measured using a bespoke adverse events questionnaire (completed by parents) at 16 weeks
9. Health-related quality of life is measured using the EQ-5DY (3L proxy) (completed by parents) at 16 and 52 weeks
10. Acceptability of the intervention is measured using a bespoke acceptability questionnaire (completed by parents in the intervention arm) at 16 weeks
11. The child's emotional and behavioural difficulties, distress and social impairment is measured using the Strengths and Difficulties Questionnaire (completed by teachers) at 16 and 52 weeks
12. Cost effectiveness is measured using a bespoke resource use questionnaire (completed by teachers) at 16 and 52 weeks
13. Safety is measured using a bespoke adverse events questionnaire (completed by teachers) at 16 weeks
14. Social and emotional competence (including perceived social skills, challenging behaviours and academic confidence) is measured using Social Skills Improvement System (SSIS) (completed by the teacher) at 52 weeks

### Completion date
31/12/2020

# Eligibility

### Key inclusion criteria
Children:
1. Is aged between 7 and 15 years (based on previous research and extensive PPI recommendations)
2. Attends a mainstream school in years 2-10
3. The child and parent/ guardian have a sufficient understanding of English to be able to provide informed consent and read the LEGO®-based therapy instructions
4. Has an ASD clinical diagnosis from a qualified assessing clinician or team [based on best-practice guidance leading to an ICD-10 (World Health Organization, 1993) or DSM-IV diagnosis (American Psychiatric Association, 2000)] as reported by the child's parent/ guardian and in the child's school records (this may include the school's special educational needs (SEN) register, an individual education plan (IEP), individual health care plan, my support plan (MSPs), education health care plans (EHCPs), individual learning plans (ILP's) or equivalent)
5. Scores 15 or higher on the Social Communication Questionnaire
6. Has the ability to follow and understand simple instructions (as determined by the associated teacher/ TA or parent/ guardian)

Schools:
1. It is a mainstream school located in Leeds, York, or Sheffield
2. It has not used LEGO®-based therapy with the child in the current or preceding school term
3. They have at least one child diagnosed with ASD (in line with child inclusion criteria above)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
260

### Key exclusion criteria
1. The school has used LEGO®-based therapy with the child in the current or preceding school term
2. They have physical impairments which would prevent them participating in the activities

### Date of first enrolment
01/09/2017

**Date of final enrolment**
30/06/2019

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**University of Sheffield**
School of Health and Related Research
Sheffield
United Kingdom
S1 4DA

# Sponsor information

**Organisation**
Leeds and York Partnership NHS Trust

**ROR**
https://ror.org/00n635c12

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Barry Wright (barry.wright1@nhs.net). Data will be available from the end of study closure which is in December 2020 for five years. This will include individual anonymised participant data and study publications including the study protocol, statistical analysis plan, health economics plan, and case report forms. Data from this study will be available via a sponsor-controlled application process for which applicants must show that they have sound scientific reasons for accessing the data and acceptable research methods. Consent for the sharing of anonymised data was obtained from all study participants.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Cost utility analysis | 17/01/2022 | 20/09/2023 | Yes | No |
| Results article | results | 30/11/2023 | 20/12/2023 | Yes | No |
| Results article | | 29/03/2025 | 10/09/2025 | Yes | No |
| Protocol article | protocol | 01/06/2019 | 19/05/2020 | Yes | No |
| Basic results | | 04/04/2022 | 21/04/2022 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |