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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
20/12/2023

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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Who is funding the study?
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

Study website
https://www.comic.org.uk/research/lego

Contact information

Type(s)
Public

Contact name
Ms Ellen Kingsley

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e.kingsley@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2017

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 240; UK Sample Size: 240

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
England

United Kingdom

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

Sponsor details

2150 Century Way
Leeds
England
United Kingdom
LS15 8ZB

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
We will begin to consider our dissemination strategy at an early stage of the project and will publish a final report around one year after our overall trial end date. We will publish the results of each phase of our study in high profile mainstream and specialist science journals, such as the British Journal of Psychiatry, the Journal of Child Psychology and Psychiatry, Clinical Child Psychology and Psychiatry and Journal of Autism and Developmental Disorders.

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 National Autistic Society and members of service user groups such as ASCEND will be consulted

in the development of methods and dissemination which will be effective in reaching 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 National Autistic Society, 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.

Towards the end of the trial, our PPI representatives will organise a meeting with stakeholders including parents and professionals working with young people with ASD to specifically discuss the dissemination of the study findings and put together a dissemination plan. This will be present at the trial management group and any additional dissemination plans will be added. We will hold a research dissemination event for national and local clinicians and policy makers. Depending on findings, we will make suggestions to NICE about treatment evidence.

We plan to publish the protocol, and it will be made available on the University of Sheffield study webpage as well once developed.

Intention to publish date
31/03/2021

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?
Protocol article	protocol	01/06/2019	19/05/2020	Yes	No
Basic results		04/04/2022	21/04/2022	No	No
Results article	Cost utility analysis	17/01/2022	20/09/2023	Yes	No
Results article	results	30/11/2023	20/12/2023	Yes	No