Play brick therapy to aid the social skills of children and young people with autism spectrum disorder: the I-SOCIALISE cluster RCT

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/VGTR7431.

Primary conflicts of interest: Gina Gomez de la Cuesta co-authored the LEGO® (LEGO System A/S, Billund, Denmark) based therapy manual that formed the basis of the intervention delivered in the trial with the permission of all co-authors. Gina Gomez de la Cuesta worked as a sole trader training professionals in LEGO® based therapy from 2015 to 2018. In 2018, Gina Gomez de la Cuesta founded Bricks for Autism CIC (now Play Included CIC), a community interest company, to continue to offer training in LEGO® based therapy, and has received a salary as an employee of the company. On 30 March 2021, the LEGO Foundation (Billund, Denmark) and Play Included CIC officially launched a partnership to scale training, awareness, accessibility and research into the Brick-by-Brick programme internationally. With the agreement of the LEGO Foundation, the term 'LEGO® based therapy' is used in this report, and any related papers or presentations, but in future research and unconnected publications the term 'Play Brick Therapy' will be used instead. Cindy Cooper is a member of the National Institute for Health and Care Research (NIHR) Clinical Trials Unit (CTU) Standing Advisory Committee (2016–present) and the UK Clinical Research Collaboration Registered Clinical Trials Units

Network Executive Group (2015–present). Simon Gilbody reports membership of the NIHR Health Technology Assessment (HTA) Efficient Study Designs (2017–20), the NIHR HTA Funding Committee Policy Group (formerly Clinical Studies Group) (2017–20), NIHR HTA Clinical Evaluation and Trials Committee (2008–14) and NIHR HTA Commissioning Committee (2016–20).

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Scientific summary

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Scientific summary

Background

Autism spectrum disorder (ASD) is a neurodevelopmental condition currently estimated to affect 1.00–1.16% of children and young people (CYP) in the UK. Autistic CYP typically experience developmental differences in social communication and may have strong specific interests/preferences and repetitive behaviours. Impacts are often seen in social functioning, general mental health and long-term social and educational outcomes into adulthood.

Social learning through friendships is an important part of a child or young person's development. It is an area in which many autistic CYP struggle because they tend to initiate and engage in social interactions differently from typically developing peers. They may prefer solitary activities with structured rules and less co-operative play and emotional exchange, which may mean that they find social interactions more challenging. Over time, autistic CYP may feel socially isolated.

A number of social interventions aim to help autistic CYP to develop these skills. CYP often find it difficult to transfer skills learnt in one context to other areas of their lives. LEGO® (LEGO System A/S, Billund, Denmark) based therapy is a group social skills intervention designed for autistic CYP to facilitate the learning and flexible practising of social skills with peers. It is designed to make social interactions interesting by using a structured and predictable toy with which CYP are often already familiar and intrinsically motivated to play.

The use of LEGO® based therapy in the UK is increasing following reported potential benefits. However, the evidence base for LEGO® based therapy is limited, with only a small number of studies assessing its use for autistic CYP. Among these, only one small study used a randomised controlled trial design to compare LEGO® based therapy with a similar social skills intervention, the Social Use of Language Programme (SULP). This study had several limitations, including a small sample size and a lack of fully randomised allocation. A scoping review of the research in this area conducted in 2017 concluded that more robustly designed studies with larger sample sizes and standardised outcome measures are needed to properly evaluate the effectiveness of LEGO® based therapy in this population.

Objectives

Primary objective

- To examine the clinical effectiveness of LEGO® based therapy groups on the social and emotional competence (specifically perceived social skills) of autistic CYP in schools, compared with usual support for autistic CYP, at 20 weeks after randomisation.

Secondary objectives

- To examine the clinical effectiveness of LEGO® based therapy groups on the perceived social isolation of autistic CYP in schools, compared with usual support for, at 20 and 52 weeks.
- To examine the clinical effectiveness of LEGO® based therapy groups on the academic competence of autistic CYP in schools, compared with usual support for autistic CYP, at 20 and 52 weeks.
- To examine the clinical effectiveness of LEGO® based therapy groups on assertion, social control, externalising and internalising in autistic CYP in the school setting, compared with usual support for autistic CYP, at 20 and 52 weeks.
- To examine the cost-effectiveness of LEGO® based therapy groups, compared with usual support for autistic CYP, at 52 weeks.

- To examine the emotional and behavioural symptoms in those receiving LEGO® based therapy, compared with usual support for autistic CYP, at 20 and 52 weeks.
- To 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 52 weeks after randomisation.
- To examine the acceptability of the intervention at follow-up points using a purpose-designed questionnaire and telephone interviews at 20 weeks.
- To examine treatment fidelity through independent observation of treatment sessions across schools and a self-report measure completed by the facilitator [i.e. a trained teacher or teaching assistant (TA)] after each session.

Setting

The setting was mainstream primary and secondary schools in the north of England.

Participants

Participants were CYP in mainstream schools between the ages of 7 and 15 years with a diagnosis of ASD, a parent or guardian of the CYP and a teacher or TA in the child or young person's school who knew them well (i.e. an associated teacher). Another school staff member was recruited in schools allocated to the intervention arm to run the LEGO® based therapy sessions (i.e. a facilitator teacher).

Participants were recruited by contact with mainstream primary and secondary schools following meetings to explain the study and confirmation of eligible CYP in their schools. Participants were included if they met study inclusion criteria and provided fully informed consent to participate.

Methods

The trial used a pragmatic cluster randomised controlled trial design. Remote randomisation of each school using stratified randomisation lists was provided by a blinded statistician from the Clinical Trials Research Unit, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK.

All participants completed a set of baseline questionnaires. Once baseline measures were completed for all participants in a school, the school was randomly allocated to one of two trial arms. Participating CYP in schools allocated to the intervention arm received 12 sessions of LEGO® based therapy in addition to usual support from their school, their general practitioner and other professionals. In schools allocated to the control arm, participating CYP received usual support only. Training was provided for intervention school staff by members of the study team and experienced local authority members trained by experts in the field. All participants were followed up 20 and 52 weeks after their school was randomised and were asked to complete similar questionnaires to those completed at baseline and questionnaires around their health resource use.

Acceptability of the interventions was assessed using a purpose-designed questionnaire and telephone interviews with parents and facilitators. Fidelity was assessed using questionnaires and video-recordings when possible.

The study team ensured the involvement of patients and the public throughout the study, including a parent of an autistic child and groups such as the Young Dynamos research advisory group (Bradford District Care NHS Foundation Trust, Shipley, UK) and the National Autistic Society (London, UK) in initial study design and specific discussions throughout the study.

Intervention

LEGO® based therapy

LEGO® based therapy is a social skills intervention designed to support CYP with social communication difficulties, such as autistic CYP, by offering playful opportunities to practise social skills. It was created by Daniel LeGoff, who observed that autistic CYP may be particularly drawn to LEGO bricks, perhaps because of their interests and strengths in systemising.

In the intervention, CYP, usually in groups of three, build LEGO sets. The CYP take turns to play one of three roles: the 'engineer', who has the instructions and communicates them to the group; the 'supplier', who finds the correct bricks; and the 'builder', who builds the model. CYP then progress to collaborative 'freestyle' building, in which they build models of their own design together. Sessions aim to be CYP led, following their interests as far as possible. Many skills are practised throughout, including communication, joint attention, problem-solving, emotion regulation and compromise. The intervention uses a naturalistic play setting, meaning that CYP learn how to collaborate with others through doing, rather than through didactic teaching.

Sessions are facilitated by an adult, who aims to guide the CYP rather than direct them explicitly. Adults are encouraged to allow CYP to solve their own challenges and to promote social problem-solving skills, stepping in to prompt through open questions when needed. CYP are encouraged to practise and role-play new social strategies discovered in the sessions. The adult's role is also to praise and highlight the positive things happening in a session, using rewards such as stickers and certificates as motivation.

Procedure

The intervention was provided in school by teachers or TAs, termed 'facilitators', who were provided with a 3-hour face-to-face training session on how to deliver the intervention. Training was provided by members of the study team and experienced professionals from each recruiting site's local authority who had been 'trained to train' school staff members by co-applicant Gina Gomez de la Cuesta and expert colleagues.

Facilitators were also provided with a brief guide specifically designed for this study, which describes the essential elements of the intervention and how to facilitate sessions successfully. Schools were given all materials needed to run their sessions, including a range of LEGO sets with instructions and freestyle bricks, funded by the research. Groups were also given 'brick club' materials, including group rules, role cards (i.e. supplier, builder or engineer), free-play building ideas and a points system chart, all of which they were encouraged to use.

Schools were asked to run 12 sessions of LEGO® based therapy over a 12-week period. It was recommended that sessions were run for 1 hour once per week for the 12-week period; however, multiple sessions in 1 week due to illness and time constraints were acceptable. Sessions less than 1 hour in duration were also acceptable, but facilitators were encouraged to run groups for at least 45 minutes.

Fidelity

Intervention fidelity was assessed via two methods: (1) completion of the self-report fidelity checklist after each session of LEGO® based therapy by all facilitators and (2) video-recording of a subset of sessions where consent to be video-recorded was obtained. Video-recordings were stratified to include sessions from three time points: early intervention sessions (sessions 1–4), mid-point intervention sessions (sessions 5–8) and later intervention sessions (sessions 9–12). The self-report fidelity checklist was designed by experts on the team and mapped onto the main components of the intervention identified in the manual and previous publications. It asked the facilitator to identify which components of the intervention had taken place. Video-recordings were completed in schools where all participating CYP, their parents/guardians and the facilitator consented to the recording. These were then

independently reviewed and assessed for fidelity to the intended intervention delivery method against the fidelity checklist. Sixteen sessions were double rated to ensure rating accuracy.

Results

The clinical effectiveness of LEGO® based therapy for autistic CYP was analysed using intention-to-treat (ITT) analysis of the teacher-completed social skills subscale of the Social Skills Improvement System (SSIS) at 20 weeks. A total of 250 participants were consented and randomised to the trial, and the primary outcome ITT analysis comprised 217 CYP (86.8%) with complete baseline and primary outcome data, with 116 in the intervention arm (91.3%) and 101 in the control arm (82.1%).

The SSIS is a behaviour rating scale widely used in national portfolio studies and has been shown to be sensitive to change. A modest positive difference on this scale of 3.74 points [95% confidence interval (CI) −0.16 to 7.63 points, p = 0.06; standardised effect size 0.18] was found for CYP in the intervention arm compared with the control arm. A per-protocol analysis, which included CYP in the intervention arm who had attended six or more intervention sessions, was also carried out and showed a slightly greater, statistically significant, difference (4.23 points, 95% CI 0.27 to 8.19 points; p = 0.036). Between-group differences in both analyses did not reach the pre-specified minimum clinically important difference (MCID) of a 9- to 10-point increase on the social skills subscale of the SSIS.

The health economics analysis showed cost-effectiveness of the intervention through both reduced service use costs and a small but significant increase in quality-adjusted life years (QALYs). There was a small reduction in school-based intervention costs and intervention costs on the whole (with reduced NHS child mental health service costs) in the intervention arm compared with the control arm. Mean QALYs as reported by parents/guardians and CYP were shown to be marginally higher (by 0.03 QALYs) in the intervention arm than in the control arm.

Fidelity to the intended intervention delivery method was measured via self-report and independent reviewers. Levels of self-reported fidelity were very good, with 99% of the core content of the intervention delivered and 91% of all content being reported as delivered. Levels of fidelity assessed by independent reviewers using video-recordings were good, with 83% of core content and 77% of all content being rated as delivered. Qualitative analysis showed good levels of acceptability of the intervention by CYP, parents/guardians and facilitators, with many schools continuing to run the intervention after the study ended.

Discussion

Limitations of the study included the fact that the primary outcome measure was completed by a teacher who did not deliver the intervention but who was not necessarily blind to the intervention. Although we obtained qualitative data from parents/carers and educators/facilitators, we had no direct impressions from the CYP themselves, although the adults consistently reported high levels of satisfaction on the part of the CYP.

Analysis of the primary outcome showed modest positive improvements in social skills, although this analysis and sensitivity analyses did not show large enough changes in social skills scores for CYP in the intervention arm to reach the pre-specified MCID. However, the primary and pre-planned sensitivity analysis of the primary outcome consistently showed a positive clinical difference, with modest standardised effect sizes between 0.15 and 0.21, and there were positive health economics and qualitative findings. This is corroborated to some extent by the fact that the difference between arms for the majority of secondary outcomes, although not statistically significant, favoured the intervention arm. The post hoc additional analysis was exploratory and was not used in drawing this overall conclusion.

Conclusions

Given the positive findings of the health economics and qualitative analyses, and the presence of a small yet positive change in social skills, consideration should be given to LEGO® based therapy and its contribution to the social skills of autistic CYP when run in a school setting. The study team recommends future research into LEGO® based therapy, particularly when run in school environments. Additional analysis showed possible avenues for exploration, including whether or not there is a greater impact of the intervention for autistic CYP in secondary schools, or for those with less severe ASD symptomatology, and when there is more than one autistic child or young person in each therapy session.

Trial registration

This trial is registered as ISRCTN64852382.

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