Protocol for a Randomised Controlled Trial and Feasibility Evaluation of a Large Language Model-Based Digital Social Interaction Programme to Improve the Social Communication Skills of Autistic Children in China

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DOI: 10.54337/aau.icdvrat26.14

Abstract

In China, 0.7% of school-aged children have autism. Access to long-term social communication intervention remains limited. We evaluate a large-language-model-based digital social interaction programme designed for autistic children in China aged between 3-8 years old. The intervention integrates social story videos with real-time LLM-driven conversational practice to enhance social communication skills. Randomized controlled trial will compare the digital intervention plus standard care, with standard care alone over 12-weeks. Primary outcomes: Vineland-3 Socialization score. Secondary measure: Social Responsiveness Scale (SRS) and Autism Behavior Checklist (ABC). We aim to provide evidence for AI-supported home-based social communication interventions for young children with autism

1. Introduction

Autism spectrum disorder (ASD) is a neurodevelopmental condition characterised by persistent deficits in social communication and social interaction, alongside restricted and repetitive behaviours (American Psychiatric Association, 2013). In China, large-scale epidemiological data remain limited, but multi-site studies suggest a prevalence of approximately 0.7% among school-aged children (Zhou et al., 2020).

Social communication impairment is one of the core characteristics of ASD, affecting social initiation, understanding of emotional cues, conversational reciprocity, and non-verbal communication (Wetherby, 2006; Wetherby et al., 2007). These characteristics influence peer relationships, academic engagement, and community participation, and are associated with increased risk of anxiety, depression, and reduced quality of life (Silveira-Zaldivar et al., 2021; Wang et al., 2025). Early effective social skills intervention is therefore essential.

Digital health technologies, such as computer-assisted tools, mobile applications, and virtual reality environments can provide structured, engaging, and repeatable learning experiences

(Battocchi et al., 2009; Ploog et al., 2013; Voss et al., 2019). Yet most existing digital tools rely on pre-programmed content and lack the dynamic, reciprocal qualities of real social interaction.

Large language models (LLMs) introduce a new paradigm. LLM-driven systems can simulate naturalistic dialogue, adapt to a child's responses, and provide consistent, patient, and personalised feedback. Early studies suggest that LLM-mediated interaction may support communication and social learning in ASD (Mishra et al., 2024). Building on this potential, the present study evaluates a digital intervention combining social story videos with LLM-based interactive dialogue to create a structured "watch-practice-reinforce" training cycle.

2. Methods

2.1. Study design

This paper presents the protocol for an ongoing randomized controlled trial with trial registration number ChiCTR2400093278, which adopts a single-centre, randomized, positive-control design. Children in the intervention group will receive the digital social interaction training in addition to standard in-person rehabilitation, while the control group will receive standard rehabilitation only. The intervention period is 12 weeks. Assessments will be conducted at baseline (T0) and post-intervention (T1). Parents in both groups will complete standardised questionnaires.

2.2. Participants

Based on prior ASD social skills and digital intervention studies, an expected effect size of $d = 0.5$ was used for power analysis ($\alpha = 0.05$, power = 0.80). A minimum of 64 participants per group is required.

Accounting for 15–20% attrition, 75 participants per group will be enrolled. Thus, a total of 150 children aged 3–8 years diagnosed with ASD will be recruited from a paediatric outpatient clinic in Beijing, China, and randomly assigned in a 1:1 ratio to either the intervention or control group. Eligible participants must have a DSM-5 diagnosis of ASD confirmed independently by two child psychiatrists, and a Childhood Autism Rating Scale (CARS) score of 30 or above. Families must use Mandarin as their primary home language, and children must be able to participate in assessments and training and have no medication use during the study period.

Children will be excluded if they present with significant sensory or motor impairments, neurological conditions such as epilepsy, severe psychiatric disorders or medical issues that could interfere with participation, or severe behavioural problems. Additional exclusion criteria include colour blindness, prior exposure to similar digital interventions, and having a sibling concurrently enrolled in the study.

As of May 2026, 42 families have been enrolled, with a 95% completion rate for baseline assessments and a median daily training adherence of 87% during the first two weeks of pilot deployment.

2.3. Intervention

Children in the intervention group will receive a large-language-model-based digital social communication training programme in addition to their ongoing in-person therapies. The system operates on an Android tablet and integrates mobile internet connectivity, speech recognition, and

LLM-driven natural language processing to create a structured and continuous social interaction training environment.

Grounded in principles of early social-cognitive development and neuroplasticity, the intervention follows a "social story video learning-LLM interactive dialogue practice" model targeting foundational social communication skills. Each day, the system delivers 8–10 short animated social story videos of approximately two minutes each. These videos depict common social scenarios relevant to young children, such as greeting others, requesting help, sharing toys, taking turns, expressing gratitude, or comforting peers, and present characters' behaviours and emotional expressions in a clear, visually accessible format. The aim is to support children's understanding of social rules and emotional cues across familiar contexts.

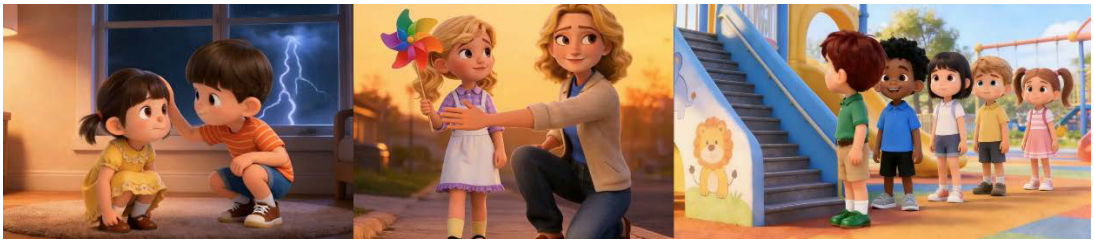

Figure 1: Social scenarios including dealing with fears of lightening, crossing busy streets and queuing to play.

Immediately after viewing the videos, children transition to an interactive dialogue module featuring a child-friendly virtual character *Maya* powered by a large language model. *Maya* engages the child in real-time conversation, interpreting spoken or typed responses and generating adaptive prompts that probe comprehension, emotion recognition, and scenario-based reasoning. Interactions may involve identifying characters' emotions, discussing appropriate behavioural responses, or relating the scenario to the child's own experiences.

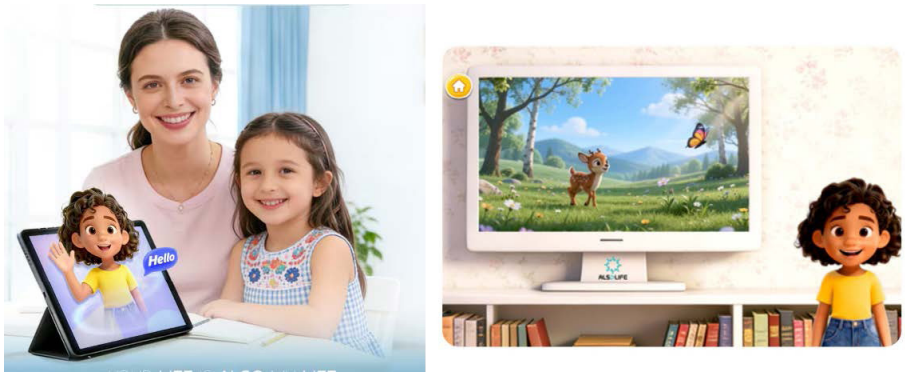

Figure 2: Maya engaging with the child in real-time conversation.

The system dynamically adjusts the difficulty of questions and conversational scaffolding based on the child's responses, and provides encouraging feedback to reinforce appropriate social communication. Training is delivered in a one-to-one digital format, with each child using an individual tablet while a parent or therapist offers minimal assistance to support device use and maintain engagement. Sessions last approximately 10–15 minutes, occur once daily, and continue for 12 weeks. The system automatically records training duration, number of interaction turns, and response content for subsequent adherence and outcome analyses. Throughout the intervention period, research staff conduct regular follow-ups to monitor progress and address technical issues.

2.4. Safety and ethical considerations

The involvement of young autistic children requires a robust safety and ethical framework. The system therefore incorporates multiple layers of protection that were developed through a co-design process involving autistic consultants, clinicians, parents, and engineers. The LLM operates within a tightly constrained domain limited to pre-approved social-communication topics and scenario-based prompts, ensuring that all dialogue remains aligned with therapeutic goals. A multi-layered filtering system combines rule-based and classifier-based detection to identify and block inappropriate, confusing, or emotionally intense outputs, and any response that falls outside the approved domain is automatically replaced with a safe, deterministic alternative.

For conversational branches involving safety, conflict, emotional distress, or uncertainty, the system uses structured and predictable templates. This reduces ambiguity, prevents hallucination-driven variability, and maintains a stable interaction pattern that is developmentally appropriate for young children. All interactions are logged, and any flagged responses are reviewed by research staff. A caregiver remains present during every session to provide additional oversight and to support engagement.

The safety architecture and interaction design were shaped by autistic consultants who participated in early prototyping and scenario review. Their insights emphasised the importance of predictable phrasing, stable conversational rhythms, and low-arousal visual design to reduce cognitive load and support emotional safety. They also highlighted the need to avoid ambiguous or metaphorical language, which can introduce unnecessary uncertainty; as a result, all dialogue is written in clear, concrete, literal terms. Consultants further noted that cultural and linguistic localisation is essential for comprehension, prompting revisions to phrasing, scenario selection, and character behaviour to ensure alignment with children's real-world environments. They also recommended the inclusion of emotionally safe pathways, including gentle redirection and the option to step away from topics that may cause discomfort.

Together, these safeguards aim to ensure that LLM-mediated interactions remain predictable, emotionally safe, culturally relevant, and developmentally appropriate for young autistic children, while maintaining the flexibility and responsiveness that make conversational AI a promising tool for social communication support.

2.5. Outcome measures

The primary outcome will be the Vineland Adaptive Behavior Scales, Third Edition (Vineland-3), a widely used caregiver-reported measure of adaptive functioning. The Vineland-3 assesses Communication, Daily Living Skills, and Socialization, with an optional Motor Skills domain for younger children. The measure yields both domain-specific standard scores and an Adaptive Behavior Composite, and is extensively used internationally and increasingly in China for evaluating functional profiles and intervention outcomes in children with ASD. Secondary outcomes will include the Autism Behavior Checklist (ABC) and the Social Responsiveness Scale (SRS). The ABC is a 57-item caregiver- or practitioner-completed checklist assessing autism-related behaviours across sensory responses, social relating, body and object use, language, and self-help skills, with higher scores reflecting greater symptom severity. The SRS is a 65-item measure of social communication difficulties and autism-related traits across five domains: social awareness, cognition, communication, motivation, and restricted behaviours. Both instruments have strong

psychometric properties and are widely used in clinical and research settings to assess behavioural characteristics and social functioning in ASD.

3. Data analysis

All primary analyses will follow an intention-to-treat (ITT) framework, including all randomized participants regardless of adherence to the digital intervention. Linear mixed models (LMMs) will be used to examine change over time in primary and secondary outcomes, specifying participant as a random intercept to account for within-subject correlation and including fixed effects for group (intervention vs control), time (baseline vs post-intervention), and the group × time interaction. Baseline score, age, sex and socioeconomics status will be entered as covariates. The primary test of efficacy will be the group × time interaction for the Vineland-3 Socialization standard score. Secondary models will be fitted for SRS and ABC scores. Effect sizes (e.g., Cohen's d) and 95% confidence intervals will be reported for between-group differences at endpoint, mirroring the approach used in our previous digital intervention trial, where a medium-to-large effect was observed on the primary adaptive outcome. Missing data will be handled under the missing-at-random assumption using maximum likelihood estimation within the LMM framework; prespecified sensitivity analyses will include multiple imputation and per-protocol analyses restricted to participants who complete a predefined minimum proportion of digital sessions. For feasibility, adherence will be summarised descriptively (e.g., proportion of planned sessions completed, mean training minutes, distribution of interaction turns), and exploratory dose–response analyses will examine whether higher engagement with the LLM system predicts greater gains in social outcomes, using additional LMMs or regression models with adherence indices as predictors.

4. Ecpected outcoms and proposed mechanisms

Based on effect sizes observed in our prior cognitive-motor digital trial and on existing social skills interventions in ASD, we anticipate a small-to-medium to medium effect (approximately Cohen's d ≈ 0.4–0.6) on Vineland-3 Socialization scores in favour of the LLM intervention, with converging but potentially smaller effects on SRS and ABC scores. We expect the intervention group to show a steeper improvement trajectory over 12 weeks than the control group, particularly among children with higher adherence to daily sessions.

Mechanistically, we hypothesise that repeated exposure to structured social stories, combined with high-frequency, low-pressure conversational practice with the LLM, will enhance social understanding, emotion recognition, and conversational reciprocity, which in turn will translate into improved everyday social functioning as captured by caregiver-reported measures. We also anticipate that the home-based, parent-supported format will strengthen generalisation of skills across settings and that exploratory analyses may reveal a dose–response pattern in which greater engagement with the digital system is associated with larger gains in social communication and adaptive behaviour.

5. Conclusion

This study addresses a critical gap in ASD intervention: the need for accessible, scalable, and interactive social communication training. Traditional in-person therapies are resource-intensive and often insufficient in frequency. Digital tools can extend learning opportunities, but most lack the dynamic reciprocity of real social interaction.

LLMs offer a novel solution by enabling naturalistic, adaptive dialogue. When combined with social story videos, the system provides both structured modelling and interactive practice. This aligns with developmental and neuroplasticity principles emphasising repeated, context-embedded learning.

If effective, the intervention could serve as a complementary home-based therapy, reducing reliance on scarce professional resources and supporting continuous practice beyond clinical settings.

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