Metaverse-based social skills training programme for children with autism spectrum disorder to improve social interaction ability: an open-label, single-centre, randomised controlled pilot trial

Joo Hyun Lee,[a,#] Tae Seon Lee,[b,c,#] Su Young Yoo,[d,e] Seung Woo Lee,[f] Ji Hye Jang,[a] Ye jin Choi,[d] and Yu Rang Park[a,*]

[a]Department of Biomedical Systems Informatics, Yonsei University College of Medicine, Seoul, South Korea
[b]Department of Neurosurgery, Yonsei University College of Medicine, Seoul, South Korea
[c]Center for Medical Education, Graduate School of Medicine, Nagoya University, Japan
[d]DoBrain Co., Ltd., Seoul, South Korea
[e]Department of Digital Health, Samsung Advanced Institute for Health Sciences and Technology (SAIHST), Sungkyunkwan University, Seoul, South Korea
[f]Graduate School of Information and Communication Technology, Ajou University, Suwon, South Korea

eClinicalMedicine 2023;61: 102072
Published Online 5 July 2023
https://doi.org/10.1016/j.eclinm.2023.102072

Summary

Background Autism spectrum disorder (ASD) is characterised by abnormalities in social interactions and restricted and repetitive behaviors. Children with high-functioning ASD (HFASD), lack social communication skills, do not interact with others, and lack peer relationships. We aimed to develop, and evaluate the feasibility of, a metaverse-based programme to enhance the social skills of children with HFASD.

Methods This open-label, single-centre, pilot parallel randomised controlled trial (RCT) was conducted on boys aged 7–12 years with HFASD. Children were recruited from a treatment centre for children with HFASD in Korea or by self-referral through online community webpages for the parents of children with HFASD. Participants were randomly assigned (1:1) by a blinded researcher to receive either four weeks of a metaverse-based social skills training programme or a control group. Randomisation was stratified by age (children aged 7–9 and 10–12 years) using permuted blocks (block size 4). The metaverse-based social skills training programme was delivered via the metaverse platforms (Roblox) and Zoom. Children in the intervention group completed the metaverse-based social skills training programme at home for four weeks. The intervention consisted of four sessions, one session per week, for 60 min each. The control group did not receive any interventions. The primary outcome measure was the median change in the Social Responsiveness Scale-2 (SRS-2) scores from pre-to post-intervention. SRS-2 is an assessment tool used to confirm the effectiveness of social interactions. Higher scores indicate lower social functioning. The trial is registered with CRIS Registration Number; KCT0006859.

Findings Between February 14, 2022, and March 31, 2022, 20 participants were enrolled. Overall, 15 children (median [Interquartile range (IQR)] age, intervention group: 9.0 [8.0–10.0]; control group: 8.5 [8.0–10.0]) participated in the programme. The intervention group included nine participants (60%), and the control group included six participants (40%). The SRS-2 total scores for the intervention group decreased from baseline 96.0 (IQR: 74.0–112.0) to post-intervention 85.0 (IQR: 84.0–103.0). The group median difference in SRS-2 scores between the intervention and control groups was 11.5 (95% CI: 8.5–14.0), with a further reduction in the intervention group. Similar trends were seen for social cognition (group median difference, 95% CI: 2.0, 1.0–4.0), social communication (group median difference, 95% CI: 2.0, 1.0–4.0), and autistic mannerism (group median difference, 95% CI: 4.0, 1.0–5.0). There were no adverse events related to study participation.

Interpretation The findings of this feasibility study suggest that children with HFASD can potentially be familiarised, through metaverse-based programmes, with real-life social situations to improve sociality and reduce emotional and behavioural problems. Such interventions could be delivered at home and possibly be extended to target groups that have difficulty in interacting with peers offline.

*Corresponding author. Department of Biomedical System Informatics, Yonsei University College of Medicine, Department of Artificial Intelligence, Yonsei University, 50-1 Yonsei-ro, Seodaemun-gu, Seoul 03722, South Korea.
E-mail address: yurangpark@yuhs.ac (Y.R. Park).
[#]Contributed equally.

Funding The Institute of Information & Communications Technology Planning & Evaluation grant, via the Ministry of Science and ICT of the South Korean Government.

Keywords: Social skill training programme; Metaverse; Digital therapeutics; Digital therapy; High functioning autism spectrum disorder; HFASD

Research in context

Evidence before this study

We searched PubMed and Google Scholar for studies on randomised controlled trials published in English using the search terms "PEERS," "Social Skills Training Program," "Social Skill Training," "HFASD," "High-Functioning Autism Spectrum Disorder," "Autism Spectrum Disorder," "Digital Therapy," "Digital Therapeutics," "Virtual Reality," "VR," and "Metaverse," with the last update on August 31, 2022. Most social skills training for children with autism spectrum disorder (ASD) were conducted offline. In some studies, sociality training programmes were conducted in a virtual environment using virtual reality (VR), but some VR devices were manufactured for children 13 years of age or older, so there is a limitation to this research. Socialisation programmes for high-functioning children with ASD using the Metaverse platform for peer-to-peer interaction in real-world-like environments are a relatively under-researched area.

Added value of this study

To the best of our knowledge, this is the first pilot randomised controlled trial to demonstrate a metaverse-based social skills training programme for children with high-functioning ASD (HFASD). Most existing social skills training programmes that use digital technology involve individual children. However, in our study, we used the Metaverse platform to create a group training programme with real children, which may show that children with HFASD can improve their social skills and reduce their emotional and behavioural problems through training in social situations. The results of this study indicate that effective social improvement interventions can be received at home, which could potentially be extended and applied to target groups that have difficulty in interacting with peers offline because of chronic diseases.

Implications of all the available evidence

This study of a 4-week intervention demonstrates the feasibility of using a metaverse-based social skills training programme to improve social ability and reduce emotional and behavioural problems in children with HFASD.

Introduction

Autism spectrum disorder (ASD) is a complex developmental disorder characterised by persistent challenges in social interaction, speech, and nonverbal communication, as well as restricted or repetitive behaviors.[1] Approximately 52 million people worldwide are reported to live with ASD, with a prevalence rate of one in every 132 individuals when compared to the total population.[2] Among them, in the children group classified as having high-functioning ASD (HFASD), there are reports that qualitative damage to social interaction may worsen in the regular curriculum. Children with HFASD generally recognise a lack of social interaction by comparing self-interest with other children and are prone to negative emotions that persist into adulthood.[3] If a child with HFASD is not exposed to proper intervention they will most likely avoid normal social contact, whereas an adult with HFASD is likely to have poor quality of employment which can lead to mental disorders.[4]

Psychotherapeutic approaches are preferred, and behavioural interventions are associated with positive outcomes for children with ASD.[5] Designed to treat ASD, Applied Behavior Analysis (ABA) is a behavioural intervention programme that focuses on observable behaviors and aims to reinforce positive behaviors and extinguish target behaviors,[6,7] but Fountain et al. (2012) reported little effectiveness in promoting socialisation.[8] The Programme for Education and Enhancement of Relational Skills (PEERS®) is an evidence-based programme that was developed to mediate HFASD. The programme was designed to help children and adolescents acquire social skills and the group treated through this programme showed improved social skills.[9,10]

Traditional treatment with qualified professional experts takes a long time, inaccessible, and expensive. According to Jennifer et al. (2016), children with ASD and their families living in rural and generally underserved areas had difficulty accessing appropriate behavioural treatments.[11] In addition, coronavirus disease-2019 (COVID-19) limited treatment opportunities for children with ASD who needed therapeutic interventions. Consequently, children who did not have

access to appropriate therapeutic interventions may have suffered from behavioural problems.[12] Therefore, it is necessary to explore alternative models of intervention using digital platforms beyond traditional treatment models. Digital interventions to improve behavior in children with ASD have been discovered in recent studies.[13] Among the various digital technology, the internet based virtual world game platform (metaverse, e.g., Roblox) provides various types of cooperative activities for children to participate creatively and socially. The Metaverse is a virtual space that people can access through different devices, such as computers, mobile devices, and game consoles.[14] It offers new directions for delivering high-quality healthcare services and treatments. In this digitally persistent environment, individuals interact and experience the shared virtual space through avatars in real-time.[15] Thus, we designed the study to use a metaverse based social interactive game platform (Roblox). Roblox, MineCraft, Whyville, and Zepeto are internet-based metaverse platforms where users can socialise, be creative, and play using their imagination.[16,17] Socialisation with peers is important for children and adolescents with ASD to build close friendships and engage in positive peer interactions. A metaverse-based interactive game platform can provide various cooperative activities where children and adolescents can participate.

We aimed to (1) develop a metaverse-based social skills training programme with a digital platform to enhance the social interaction skills of children with HFASD, and (2) evaluate the feasibility of the developed programme within the metaverse as part of the PEERS, as well as improve social interaction skills essential for children with HFASD.

Methods

Study design

The metaverse-based social skills training programme for children with HFASD aged 7–12 years to improve social interaction is a parallel group, open-label, single-centre, pilot randomised controlled trial (RCT; trial registration: KCT 0006859). It follows the Consolidated Standards of Reporting Trials (CONSORT) pilot checklist.[18] In this study, based on PEERS, we designed and applied a social skills training programme for children with HFASD that can be used within the metaverse platform. Participants were publicly recruited through a treatment centre for children with HFASD or online community webpages for parents of children with HFASD. The trial protocol was published in an online journal.[19] At Visit 1, participants were personally visited and underwent the Korean-Wechsler Intelligence Scale for Children-IV (K-WISC-IV) test for enrollment in the clinical trial, as well as demographic characteristics and pre-neuropsychology tests. The mental states of the parents and caregivers were measured. The children eligible for this study were randomly assigned to the intervention or control groups at a 1:1 ratio for four weeks. Children and their parents in the intervention and control groups were administered the same assessment in the pre- and post-tests, and the intervention group was provided with a metaverse-based PEERS for four weeks, while the control group did not receive any interventions. Participants completed the outcome measure after the intervention session. The participants, parents, and caregivers received a post-intervention neuropsychological test questionnaire via mail, which they responded to at home and returned to the research team via mail (Fig. 1A).

Written informed consent was obtained from all children and parents who participated in this study. This study was approved by the Korea National Institute for Bioethics Policy (KONIBP), a public institutional review board (P01-202202-01-017).

Participants

Children were recruited from February to March 2022 from a treatment centre for social ability development for children with HFASD in Korea or by self-referral through online community webpages for the parents of children with HFASD. Inclusion criteria for children were as follows: (a) between 7 and 12 years of age; (b) diagnosed with ASD; (c) can understand the rules, and have a IQ $\geq$ 90 according to a standardised intelligence test; (d) children and parents who are fluent in the Korean language; (e) no defects in motor function; and (e) self or guardians who can use a tablet, PC and desktop, or laptop computer to browse the Internet. The following were the exclusion criteria for children: (a) speech, hearing, or visual impairments; (b) history of congenital or acquired brain damage, such as cerebral palsy; (c) difficulty in cooperating with programme participants because of serious developmental delays; (e) difficulties in controlling behavior; or (f) medicine intake or environmental change occurred during the intervention. All participants provided written informed consent including children and legal guardians (see Supplementary 2 for the consent form).

Randomisation and masking

The study randomly assigned participants (1:1) to either a metaverse-based social skills training programme (intervention group) or no intervention (control group). Prior to the study, researchers conducted randomisation among children who met the inclusion criteria. An independent statistician from a different institution created the randomisation codes using blocked randomisation (with a block size of 4) and age stratification (7–9 years and 10–12 years) and delivered them to the researchers as a password-protected zip file to reduce exposure. The independent statistician used the PROC PLAN procedure in SAS version 9.4 to generate the

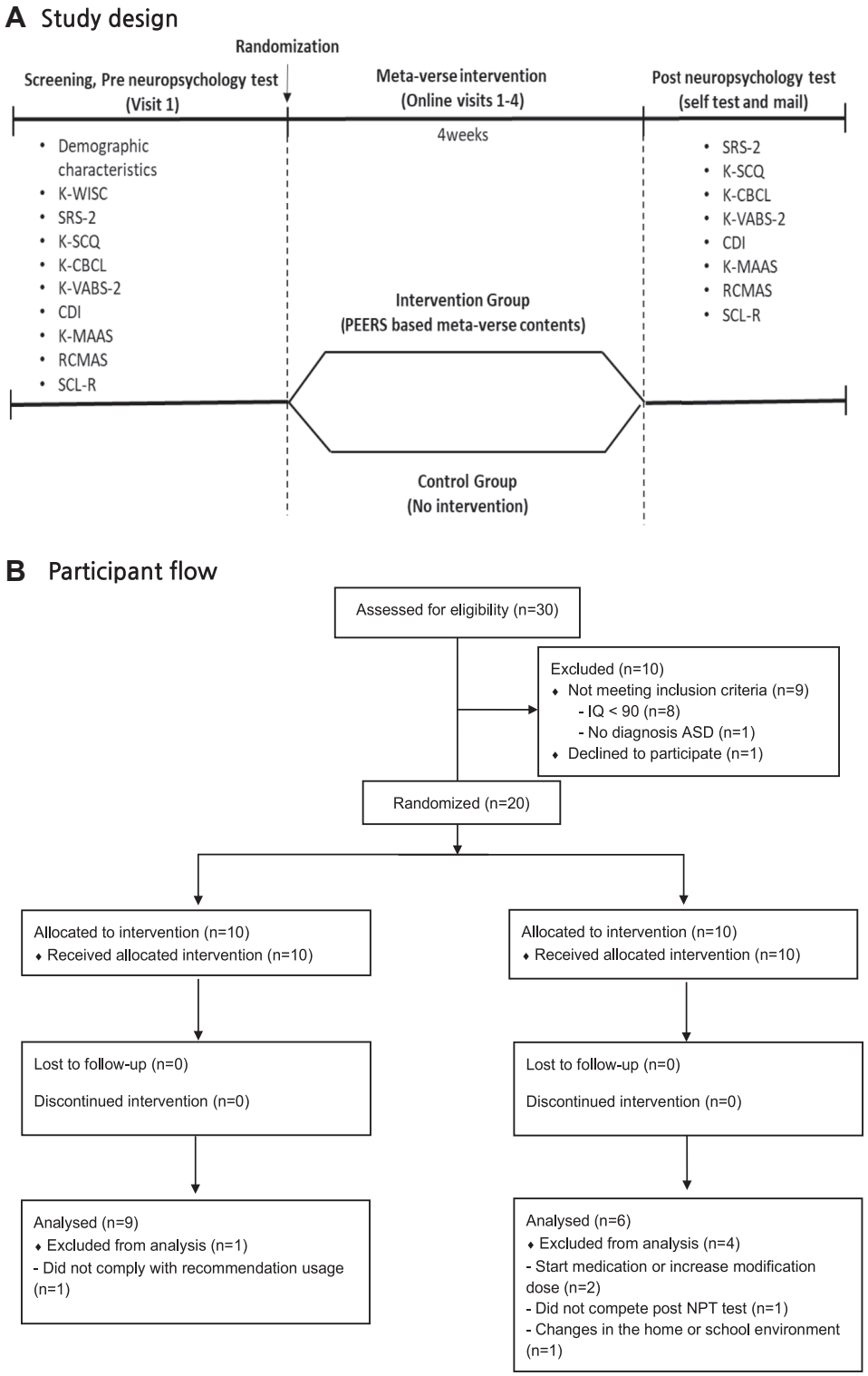

Fig. 1: Study profile: study design (A) and participant flow (B). K-WISC: Korean-Wechsler Intelligence Scale for Children, SRS-2: Social Responsiveness Scale-2, K-SCQ: Korean versions of the Social Communication Questionnaire, K-CBCL: Korean Child Behavior Checklist, K-VABS-2: Korea Vineland-II, CDI: Children's Depression Inventory, K-MAAS: Korean version of the Mindful Attention and Awareness Scale, RCMAS: Revised Children's Manifest Anxiety Scale, SCL-R: Symptom Checklist Revision, ASD: Autism Spectrum Disorder, NPT: Neuropsychological test.

randomisation codes. The researchers used these codes to perform the randomisation.

Sample size

As this is a pilot trial, a formal calculation for sample size is not necessary, but we did follow Whitehead et al. (2016)[20] method to calculate the sample size for the pilot trial. We aimed for a sample size of 12 participants per group with 80% power and a two-sided significance level of 5%, assuming that the effect size and mean difference would be higher due to the better accessibility and more frequent interventions compared to existing offline social skills training interventions and this study is a pilot study.

Metaverse-based social skills training programme

For children with HFASD, to build friendships and engage in positive interactions, socialisation with peers is important. Children can participate in various group activities on metaverse-based interactive game platforms. The metaverse-based social skills training programme implemented PEERS within the metaverse platform for children with ASD.[9,10] The programme curriculum consisted of four sessions. The first session was the introduction and awareness of the need for rules and results. The second session involved understanding the situations based on behavior and participating in team activities. The third session included responding appropriately to negative behavioural experiences and emotions. The fourth session concerned knowing and accepting individual differences. Each session consisted of theoretical classes, practice of metaverse, homework, and feedback. Details of the programme are provided in Appendix A and B, and Table S1 in Supplementary 1.

Procedure

The metaverse-based social skills training programme was delivered via the metaverse platform, Roblox and Zoom. Participants and their caregivers accessed the study intervention using a unique username and password. Children in the intervention group completed the metaverse-based social skills training program me at home in four weeks. The intervention consisted of four sessions, one session per week for 60 min each. Each session included a target lesson, direct instruction, and practical training (metaverse) accompanied by homework to encourage skill generalisation in real-world settings. The programme was conducted by a clinical psychologist (main therapist) and two nurses (assistant therapists). The main therapist conducted the programme, and two assistant therapists observed and recorded the programme. Homework was reviewed at the beginning of each session. After the homework review and discussion, rules were set to be followed in the sports game on the metaverse platform. The participants then received didactic lessons on social skills and mindfulness from a trained therapist. A metaverse sports game was played to practice newly learned skills and rules. A screenshot of the metaverse-based social skills training programme is shown in Figure S1 in Supplementary 1. The children in the control group did not receive any intervention. All participants, including those receiving the intervention, continued with their usual treatment during the trial.

Outcomes

Neuropsychological test (NPT)

The primary outcome measure was the median change in the Social Responsiveness Scale-2 (SRS-2) scores from pre-to post-intervention. SRS-2 is an assessment tool used to confirm the effectiveness of social interactions.[21] The secondary outcomes measured in this study consisted of changes in the Korean versions of the Social Communication Questionnaire (K-SCQ),[22] Korean Child Behavior Checklist (K-CBCL),[23] Korea Vineland-II (K-VABS-2),[24] Symptom Checklist Revision (SCL-R),[25] Children's Depression Inventory (CDI),[26] Revised Children's Manifest Anxiety Scale (RCMAS),[27] and Korean version of the Mindful Attention and Awareness Scale (K-MAAS)[28] were used to evaluate pre- and post-interventions. The K-SCQ, K-CBCL, and K-VABS-2 were used to assess the reduction in social adaptation and emotional and behavioural problems in children. CDI, RCMAS, and K-MAAS tests were performed to assess improvement in children's mental health status. The SCL-R measured caregivers' psychiatric symptoms.

Biometric information

The study involved the use of a wearable device, in the form of a smartwatch (Fitbit charge 5), to collect biometric information from all participating children. The watch was chosen to minimise discomfort. Additionally, a webcam was used to record the children's behavior and facial expressions in real-time during the programme.

Data management

The data collected in this study were not viewed by anyone other than the researcher in charge of the participants' safety, nor was it leaked. In addition, data entered into the computerised system were kept confidential with all security functions turned on. This data, except for information supplied by research institutes, are inaccessible and cannot be accessed, or leaked, by anyone other than the licensed accountable researchers. Furthermore, per Article 15 of the Bioethics Act Enforcement Rules, all research-related records will be kept for 3 years after the study's conclusion, and data relating to personal information will be destroyed per Article 16 of the Personal Information Protection Act Enforcement Decree.

Statistical analysis

All outcomes in participants who completed the peer programme period and assessment at baseline and post-intervention were analysed. Participants without protocol violations (per-protocol analysis set) were included in the analysis.[29] Non-parametric analyses were used in this study because of the non-normal distribution and small sample size of the data. All baseline demographic characteristics of the participants and their neuropsychological test outcomes at baseline and post-intervention were summarised by randomised groups using the median (Interquartile range (IQR)) for continuous data or count (%) for categorical data. In the statistical analysis, we assessed the pre- and post-intervention NPT scores for the intervention and control groups and calculated the median values and IQR for each group and time point. To evaluate the significance of the intervention, we used the non-parametric bootstrap approach with fundamental bootstrap confidence intervals to estimate the 95% confidence intervals (CI) for the median difference between pre- and post-intervention in the intervention and control groups. In addition, we employed a bootstrap method to calculate the 95% CI for the median difference between the groups in terms of the difference in pre- and post-outcomes. Non-parametric bootstrap and 95% CI calculations were performed using the NumPy (version 1.23.5) package in Python (version 3.9.12). A 95% CI that includes zero indicates a lack of statistically significant difference, while a CI that does not include zero indicates a statistically significant difference. This method involved resampling with replacement from the initial dataset and determining the median for every resampled dataset. We conducted 10,000 iterations of this procedure to generate a distribution of median differences and subsequently computed the confidence intervals using the basic bootstrap method. To analyse the change in heart rate by session, we calculated the mean and standard deviation (SD) values for the heart rate measurements in each session of the intervention group, which were obtained using a wearable device (Fitbit charge5). For analysis, we used pandas (version 1.1.5), NumPy (version 1.17.0), seaborn (version 0.11.2), and matplotlib (version 3.1.2) in python (version 3.6.8). For sensitivity analysis, we performed stratification into lower and higher grades to assess the feasibility of the intervention within these subgroups. Within these subgroups, we evaluated the pre- and post-intervention NPT scores for each grade using a non-parametric bootstrap method. This allowed us to calculate the median values and IQR for each grade and time point. By performing 10,000 iterations of resampling with replacement from the original dataset, we created a distribution of median differences, from which we computed the 95% CI for these differences using the basic bootstrap method. In addition, we computed the CI for the median difference between pre- and post-intervention in the lower and higher grade groups and between the groups in terms of the differences in pre- and post-intervention outcomes. No post-hoc analyses were performed, and we did not employ any correction methods for multiple comparisons in this study. The choice of these statistical tests was primarily predicated upon the small sample size and the non-normal distribution characteristics of our data, in addition to the necessity to estimate CIs to compare the intervention and control groups. Data analysis was performed using the R software (version 4.1.0) and Python (version 3.6.8 and 3.9.12).

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Participant characteristics

Between February 14, 2022, and March 31, 2022, 20 participants who met our inclusion criteria were enrolled and randomly assigned to one of two groups. One participant in the intervention group who did not complete the recommended usage was excluded from the analysis. In the control group, several participants were excluded from analysis. This included one participant who started medication along with psychiatric treatment because they were exposed to school violence, one who increased their medication dosage as a result of increased symptoms due to the new environment at the start of the school year, one who did not complete the post-neuropsychological test, and one who changed home or school environment during the trial period. Finally, 15 participants overall were included in the data analysis (Fig. 1B).

Demographic and baseline variables were compared between the intervention and control groups prior to the intervention. Of the 15 children, nine (60%) were in the intervention group, and six (40%) in the control group. Regarding sex and ethnicity, there was no significant difference between the groups; 100% of the participants in both groups were boys and Asians. There was no significant difference between the intervention and control groups in demographic variables, including age and K-WISC-IV. Except for K-MAAS, there was no significant difference between the two groups in the neuropsychological test. The demographic and baseline variables of both groups are summarised in Table 1. The full table is presented in Table S2, Supplementary 1. We have also included a supplementary 1, Table S3, which provides demographic and baseline information for the entire sample using an intention-to-treat (ITT) analysis approach. The results of this ITT analysis did not reveal any significant differences compared to the findings

Characteristics	Group	
	Intervention (N = 9)	Control (N = 6)
Sex, n (%)		
- Male	9 (100.0%)	6 (100.0%)
- Female	0 (0.0%)	0 (0.0%)
Age, median (IQR)	9.0 (8.0; 10.0)	8.5 (8.0; 10.0)
Ethnicity, n (%)		
- Asian	9 (100.0%)	6 (100.0%)
K-WISC-IV, median (IQR)		
- Full scale IQ	100.0 (95.0; 101.0)	116.5 (100.0; 124.0)
- VCI (Verbal Compression Index)	104.0 (96.0; 119.0)	121.0 (112.0; 124.0)
Children measures		
K-MAAS (Total), median (IQR)	71.0 (61.0; 80.0)	85.5 (79.0; 91.0)
CDI (Total), median (IQR)	14.0 (8.0; 14.0)	8.5 (5.0; 11.0)
RCMAS (Total), median (IQR)	15.0 (7.0; 16.0)	8.5 (7.0; 16.0)
Parents' measures (for children), median (IQR)		
SRS-2	96.0 (74.0; 112.0)	74.5 (59.0; 87.0)
K-SCQ (Total)	9.0 (4.0; 12.0)	6.0 (3.0; 16.0)
K-CBCL (Total)	67.0 (63.0; 78.0)	69.5 (66.0; 76.0)
K-VABS-2		
- Communication	84.0 (74.5; 93.0)	81.5 (75.0; 103.0)
- Daily living skills	84.0 (77.0; 87.0)	86.5 (84.0; 89.0)
- Socialization	72.0 (68.0; 76.0)	70.5 (65.0; 75.0)
Parents' measures (for parents), median (IQR)		
SCL-R		
- Depression	49.0 (41.0; 51.0)	48.0 (45.0; 54.0)
- Anxiety	52.0 (48.0; 61.0)	52.5 (45.0; 56.0)
- Panic	45.0 (45.0; 53.0)	45.0 (45.0; 45.0)
- Agoraphobia	44.0 (44.0; 50.0)	47.0 (44.0; 50.0)
- Obsessive	49.0 (49.0; 59.0)	52.5 (44.0; 57.0)
- Obsessive-compulsive personality	51.0 (49.0; 57.0)	51.0 (46.0; 57.0)
- PTSD	47.0 (42.0; 48.0)	45.0 (43.0; 48.0)
- Anger attack	54.0 (48.0; 55.0)	51.5 (44.0; 54.0)
- Somatic	47.0 (44.0; 52.0)	49.0 (38.0; 49.0)
- Mania	55.0 (49.0; 58.0)	41.0 (38.0; 44.0)
- Paranoia	46.0 (43.0; 48.0)	51.0 (44.0; 53.0)
- Psychosis	42.0 (42.0; 46.0)	48.0 (42.0; 50.0)
- Suicide	41.0 (40.0; 46.0)	46.0 (41.0; 50.0)
- Addiction	46.0 (44.0; 63.0)	46.0 (46.0; 47.0)
- Sleep disorder	56.0 (46.0; 61.0)	46.0 (41.0; 56.0)
- Interpersonal sensitivity	50.0 (47.0; 54.0)	57.5 (56.0; 65.0)
- Regulation problem	48.0 (48.0; 52.0)	52.5 (44.0; 55.0)

IQR: Interquartile range, K-WISC: Korean-Wechsler Intelligence Scale for Children, IQ: Intelligence Quotient, K-MAAS: Korean version of the Mindful Attention and Awareness Scale, CDI: Children's Depression Inventory, RCMAS: Revised Children's Manifest Anxiety Scale, SRS-2: Social Responsiveness Scale-2, K-SCQ: Korean versions of the Social Communication Questionnaire, K-CBCL: Korean Child Behavior Checklist, K-VABS-2: Korea Vineland-II, SCL-R: Symptom Checklist Revision.

Table 1: **Demographic and baseline variable for intervention and control groups (a version of Per Protocol).**

obtained from the Per Protocol (PP) analysis. The details can be found in the Supplementary Materials.

Primary outcome

The results for the SRS-2 scores are shown in Table 2. The SRS-2 indicates that the lower the score, the better the social interaction ability. The SRS-2 total scores for the intervention group decreased from baseline 96.0 (IQR: 74.0–112.0) to post-intervention 85.0 (IQR: 84.0–103.0). The median difference in SRS-2 scores between the intervention and control groups was 11.5 (95% CI: –2.5 to 15.5), with further reduction in the intervention group. Scores on social awareness, social cognition, social communication, social motivation, and autistic mannerism decreased post-intervention (median (IQR): 11.0 [11.0–13.0], 19.0 [15.0–21.0], 31.0

Characteristics	Intervention (n = 9)		Control (n = 6)		Median difference (Median, 95% CI)[a]
	Baseline (Median, IQR)	Post (Median, IQR)	Baseline (Median, IQR)	Post (Median, IQR)	
Primary outcomes					
SRS-2 (Total)[b]	96.0 [74.0; 112.0]	85.0 [84.0; 103.0]	74.5 [59.0; 87.0]	69.5 [61.0; 95.0]	11.5 (8.5–14.0)
- Social awareness	12.0 [9.0; 13.0]	11.0 [11.0; 13.0]	9.0 [7.0; 10.0]	9.0 [7.0; 11.0]	1.0 (0.0–2.0)
- Social cognition	20.0 [18.0; 22.0]	19.0 [15.0; 21.0]	15.0 [14.0; 18.0]	16.0 [13.0; 18.0]	2.0 (1.0–4.0)
- Social communication	33.0 [26.0; 39.0]	31.0 [25.0; 35.0]	24.0 [20.0; 30.0]	23.5 [20.0; 35.0]	2.0 (1.0–4.0)
- Social motivation	13.0 [10.0; 19.0]	11.0 [10.0; 17.0]	13.5 [4.0; 18.0]	13.0 [4.0; 18.0]	1.5 (1.0–2.5)
- Autistic mannerism	18.0 [16.0; 23.0]	16.0 [13.0; 18.0]	12.0 [9.0; 14.0]	12.0 [10.0; 14.0]	4.0 (1.0–5.0)
Secondary outcome					
CDI (Total)[b]	14.0 [8.0; 14.0]	9.0 [5.0; 14.0]	8.5 [5.0; 11.0]	6.0 [4.0; 10.0]	3.0 (−1.0 to 4.0)
- Negative Self-Esteem	6.0 [3.0; 7.0]	7.0 [2.0; 8.0]	3.0 [2.0; 5.0]	2.5 [2.0; 5.0]	1.5 (−1.0 to 3.0)
- Interpersonal Problems	3.0 [2.0; 5.0]	2.0 [1.0; 2.0]	1.5 [0.0; 3.0]	2.0 [1.0; 4.0]	2.0 (1.0–3.0)
- Negative Mood/Physical symptoms	4.0 [2.0; 5.0]	2.0 [1.0; 5.0]	3.0 [2.0; 3.0]	1.0 [1.0; 3.0]	−1.0 (−2.0 to 0.0)
K-MAAS[b]	71.0 [61.0; 80.0]	66.0 [36.0; 77.0]	85.5 [79.0; 91.0]	75.5 [53.0; 80.0]	−10.0 (−15.0 to −1.5)
RCMAS (Total)[b]	15.0 [7.0; 16.0]	14.0 [11.0; 17.0]	8.5 [7.0; 16.0]	14.0 [7.0; 19.0]	3.0 (0.0–4.5)
- Over worry	2.0 [2.0; 4.0]	2.0 [2.0; 4.0]	2.5 [2.0; 4.0]	5.0 [2.0; 5.0]	0.0 (−1.0 to 2.0)
- Sensitiveness	3.0 [1.0; 3.0]	3.0 [3.0; 4.0]	1.0 [1.0; 4.0]	2.5 [2.0; 5.0]	0.5 (0.0–1.0)
- Negative Emotions/Attention Problems	3.0 [3.0; 6.0]	4.0 [4.0; 5.0]	3.0 [1.0; 5.0]	3.5 [2.0; 6.0]	1.0 (0.0–2.0)
K-SCQ (Total)[b]	9.0 [4.0; 12.0]	7.0 [6.0; 11.0]	6.0 [3.0; 16.0]	5.5 [5.0; 11.0]	0.5 (−1.5 to 3.0)
K-CBCL (Total)[b]	67.0 [63.0; 78.0]	63.0 [61.0; 70.0]	69.5 [66.0; 76.0]	68.0 [61.0; 71.0]	3.5 (−0.5 to 6.0)
- Anxiety/Depression	62.0 [62.0; 75.0]	57.0 [53.0; 72.0]	67.5 [62.0; 77.0]	69.5 [59.0; 73.0]	5.5 (1.0–6.5)
- Social problems	79.0 [67.0; 79.0]	70.0 [67.0; 72.0]	67.5 [65.0; 70.0]	66.0 [64.0; 70.0]	4.0 (0.0–7.0)
- Thought problems	68.0 [63.0; 73.0]	68.0 [59.0; 69.0]	68.0 [66.0; 70.0]	67.5 [63.0; 69.0]	1.5 (0.0–3.5)
- Aggressive behavior	62.0 [50.0; 66.0]	62.0 [50.0; 66.0]	65.5 [61.0; 70.0]	62.0 [57.0; 67.0]	−0.5 (−5.0 to 1.0)
- Internalizing problems	66.0 [63.0; 82.0]	62.0 [55.0; 72.0]	66.0 [61.0; 76.0]	65.0 [61.0; 74.0]	4.0 (0.5–7.5)
- Externalizing problems	62.0 [51.0; 65.0]	62.0 [48.0; 65.0]	65.0 [62.0; 67.0]	63.0 [58.0; 66.0]	2.0 (−2.5 to 3.5)
K-VABS-2[c]					
- Communication	84.0 [75.0; 93.0]	86.0 [75.0; 97.0]	81.5 [75.0; 103.0]	89.0 [72.0; 104.0]	−2.5 (−6.5 to 3.0)
- Daily living skill	84.0 [77.0; 87.0]	82.0 [80.0; 94.0]	86.5 [84.0; 89.0]	83.0 [81.0; 84.0]	−5.0 (−9.0 to 2.0)
- Socialization	72.0 [68.0; 76.0]	75.0 [72.0; 81.0]	70.5 [65.0; 75.0]	74.0 [65.0; 79.0]	0.0 (−2.5 to 5.0)
Parents' measures (for parents)					
SCL-R[b]					
- Depression	49.0 [41.0; 51.0]	43.0 [41.0; 48.0]	48.0 [45.0; 54.0]	51.0 [47.0; 65.0]	7.0 (1.5–9.5)
- Anxiety	52.0 [48.0; 61.0]	52.0 [42.0; 54.0]	52.5 [45.0; 56.0]	52.5 [49.0; 56.0]	5.0 (1.5–8.5)
- Obsessive compulsive personality	51.0 [49.0; 57.0]	49.0 [45.0; 55.0]	51.0 [46.0; 57.0]	51.0 [51.0; 59.0]	6.0 (0.5–12.0)
- PTSD	47.0 [42.0; 48.0]	48.0 [47.0; 48.0]	45.0 [43.0; 48.0]	48.0 [48.0; 70.0]	4.5 (−1.0 to 11.5)
- Anger attack	54.0 [48.0; 55.0]	45.0 [41.0; 57.0]	51.5 [44.0; 54.0]	50.0 [44.0; 63.0]	6.5 (−1.0 to 9.0)
- Somatic	47.0 [44.0; 52.0]	39.0 [36.0; 41.0]	49.0 [38.0; 49.0]	51.5 [51.0; 52.0]	10.0 (8.0–11.0)
- Mania	55.0 [49.0; 58.0]	53.0 [49.0; 58.0]	41.0 [38.0; 44.0]	44.0 [43.0; 44.0]	5.0 (0.0–6.0)
- Paranoia	46.0 [43.0; 48.0]]	43.0 [40.0; 53.0]	51.0 [44.0; 53.0]	52.5 [47.0; 56.0]	4.0 (0.0–4.0)
- Psychosis	42.0 [42.0; 46.0]	42.0 [42.0; 49.0]	48.0 [42.0; 50.0]	44.5 [42.0; 58.0]	0.0 (−2.0 to 4.0)
- Sleep disorder	56.0 [46.0; 61.0]	41.0 [40.0; 51.0]	46.0 [41.0; 56.0]	41.0 [41.0; 51.0]	8.0 (5.0–13.0)
- Interpersonal sensitivity	50.0 [47.0; 54.0]	47.0 [43.0; 54.0]	57.5 [56.0; 65.0]	63.5 [50.0; 69.0]	8.0 (5.0–11.0)
- Regulation problem	48.0 [48.0; 52.0]	57.0 [41.0; 61.0]	52.5 [44.0; 55.0]	53.5 [44.0; 57.0]	4.0 (−4.5 to 8.0)

SRS-2: Social Responsiveness Scale-2, CDI: Children's Depression Inventory, K-MAAS: Korean version of the Mindful Attention and Awareness Scale, RCMAS: Revised Children's Manifest Anxiety Scale, K-SCQ: Korean versions of the Social Communication Questionnaire, K-CBCL: Korean Child Behavior Checklist, K-VABS-2: Korea Vineland-II, SCL-R: Symptom Checklist Revision. [a]Median difference score between the intervention (baseline and post-intervention) and control (baseline and post-intervention) groups and 95% confidence interval were estimated using 10,000 bootstrap samples. [b]Lower scores indicate increased ability. [c]Higher scores indicate increased ability.

Table 2: **Comparison between outcome variables for the intervention and control groups (a version of Per Protocol).**

[25.0–35.0], 11.0 [10.0–17.0], 16.0 [13.0–18.0]) compared to baseline (median (IQR): 12.0 [9.0–13.0], 20.0 [18.0–22.0], 33.0 [26.0–39.0], 13.0 [10.0–19.0], 18.0 [16.0–23.0]). Supplementary 1 Table S4 presents the full table, and Figure S2 presents the plot for the primary outcome.

Secondary outcome

The CDI, RCMAS, K-CBCL, and SCL-R indicate that the lower the score, the better the ability, and K-VABS indicates that the higher the score, the better the ability. The results for the secondary outcomes are in Table 2. The full table and plots are shown in supplementary 1 and Figure S2 and Table S4.

Mental health status

The Children's mental health was evaluated using the CDI, K-MAAS, and RCMAS. The CDI total scores for the intervention group decreased from baseline 14.0 (IQR: 8.0–14.0) to post-intervention 9.0 (IQR: 5.0–14.0). In comparison to the control group, the intervention group's median Interpersonal problems score difference reduced to 2.0 (95% CI: 1.0–3.0). And the median difference of K-MAAS decreased by –10.0 (95% CI: –15.0 to 1.5) in the intervention group compared to the control group. The median difference in total RCMAS was a 3.0 (95% CI: 0.0–4.5) decrease from the control group in the intervention group.

Social adaptation and emotional and behavioural problems

In the intervention group, the total K-SCQ score tended to decrease post-intervention (median (IQR): 7.0 [6.0–11.0]) compared to the baseline (median (IQR): 9.0 [4.0–12.0]). Compared to the K-CBCL total score at baseline (median (IQR): 67.0 [63.0–78.0]), it tended to decrease post-intervention (median (IQR): 63.0 [61.0–70.0]). However, the socialisation score of K-VABS-2 increased from 72.0 (IQR: 68.0–76.0) to 75.0 (IQR: 72.0–81.0) post-intervention.

Caregiver's psychiatric symptoms

The SCL-R shows the caregiver's psychiatric symptoms. According to the results obtained, the post-intervention score for Depression was 43.0 (IQR: 41.0–48.0) in the intervention group and 51.0 (IQR: 47.0–65.0) in the control group. The estimated median difference between the intervention and control groups for Depression was 7.0 (95% CI: 1.5–9.5), Anxiety was 5.0 (95% CI: 1.5–8.5), Somatic was 10.0 (95% CI: 8.0–11.0) and sleep disorder was 8.0 (95% CI: 5.0–13.0).

Biometric information

The mean heart rate in the intervention group during the programme, as measured by a wearable device (Fitbit charge5), was 87.0 (SD: 11.0) in session 1, 94.2 (SD: 13.7) in session 2, 85.9 (SD: 9.6) in session 3, and 93.5 (SD: 11.8) in session 4 (Supplementary Figure S5). The results indicated no significant differences in heart rate measurements between sessions during the programme.

Comparison between lower- and higher-grade groups

The results of the comparison between the lower- and higher-grade groups of the intervention group are shown in Tables 3 and Table S5 in Supplementary 1. The difference between pre and post SRS total scores for the lower-grade group was –8.0 (95% CI: –12.0 to 15.0), while the higher-grade group had a difference of –9.0 (95% CI: –41.0 to 2.0). The median difference between the two subgroups, Control (post-pre) - Intervention (post-pre), was 11.5 (95% CI: 7.0–17.0). Median differences between subgroups showed a treatment effect in the higher-grade group for Autistic mannerism (Subgroup median difference; 95% CI, 12.0, 10.5–13.0), K-MAAS total (Subgroup median difference; 95% CI, 21.0, 12.5–23.0), K-SCQ total (Subgroup median difference; 95% CI, 9.0, 8.0–10.0), K-CBCL total (Subgroup median difference; 95% CI, 5.0, 3.0–7.0), Aggressive behavior (Subgroup median difference; 95% CI, 11.0, 10.0–13.0), Externalising problems (Subgroup median difference; 95% CI, 11.0, 9.0–14.0), and Socialisation (Subgroup median difference; 95% CI, 14.0, 11.0–17.0). However, CDI total (Subgroup median difference; 95% CI, –11.0, –15.0 to –9.0), Interpersonal problem (Subgroup median difference; 95% CI, –4.0, –4.0 to –3.0), Negative Mood/Physical Symptoms (Subgroup median difference; 95% CI, –5.0, –6.0 to –4.0), and Communication (Subgroup median difference; 95% CI, –10.5, –14.5 to –5.0) seemed to be more effective in the lower-grade group.

Statement on harm

There were no serious intervention-related adverse events of discontinuations due to adverse events in either group (Table 4).

Discussion

In this study, we confirmed the feasibility of a metaverse-based social skills training programme to improve social abilities and reduce emotional and behavioural problems in children with HFASD following a 4-week intervention. Specifically, our study demonstrated the potential of metaverse-based interventions to improve social interaction skills, enhance mental health outcomes, reduce emotional and behavioural problems in children with HFASD, and alleviate parental psychological distress. The results of this study are consistent with those of previous offline PEERS. Previous offline PEERS have shown significant improvements in social skills and frequency of social engagement, while also reducing emotional and behavioural problems.[9,10] However, studies have shown limitations of offline treatment, such as a long waiting time, an imbalance between urban and rural areas, and a lack of therapists.[11] This condition has been aggravated by the COVID-19 pandemic.[12] This study attempted to overcome the limitations of offline interventions, such as the accessibility of using the metaverse, and demonstrated the potential of group interventions based on the PEERS programme using the metaverse to improved social skills.

Characteristics	Lower-grade		Higher-grade		Subgroup median difference (95% CI)[b]
	Intervention (n = 5) (Median difference (95% CI))[a]	Control (n = 4) (Median difference (95% CI))[a]	Intervention (n = 4) (Median difference (95% CI))[a]	Control (n = 2) (Median difference (95% CI))[a]	
Primary outcome					
SRS-2 (Total)[c]	−8.0 (−12.0 to 15.0)	3.5 (−10.0 to 8.0)	−9.0 (−41.0 to −2.0)	5.0 (0.0–10.0)	11.5 (7.0–17.0)
- Social awareness	0.0 (−3.0 to 5.0)	0.0 (−1.0 to 3.0)	−1.5 (−3.0 to 1.0)	1.5 (−2.0 to 5.0)	3.0 (2.0–4.0)
- Social cognition	−3.0 (−6.0 to 5.0)	1.5 (−5.0 to 2.0)	−0.5 (−12.0 to 2.0)	2.5 (2.0–3.0)	3.0 (1.0–4.5)
- Social communication	−3.0 (−4.0 to 3.0)	2.5 (−3.0 to 5.0)	−0.5 (−11.0 to 4.0)	0.0 (−2.0 to 2.0)	−2.0 (−4.0 to −0.5)
- Social motivation	−2.0 (−2.0 to 1.0)	1.0 (−1.0 to 2.0)	−2.0 (−4.0 to 1.0)	−2.0 (−5.0 to 1.0)	−2.0 (−3.0 to −1 0.0)
- Autistic mannerism	0.0 (−4.0 to 4.0)	−1.0 (−6.0 to 1.0)	−7.0 (−13.0 to −3.0)	3.0 (2.0–4.0)	12.0 (10.5–13.0)
Secondary outcome					
CDI (Total)[c]	−5.0 (−11.0 to 3.0)	1.0 (−2.0 to 9.0)	1.0 (−6.0 to 16.0)	−3.5 (−6.0 to −1.0)	−11.0 (−15.0 to −9.0)
- Negative Self-Esteem	1.0 (−4.0 to 3.0)	0.0 (−1.0 to 6.0)	−0.5 (−4.0 to 15.0)	0.0 (0.0–0.0)	−1.0 (−3.5 to 0.0)
- Interpersonal Problems	−1.0 (−4.0 to 1.0)	1.5 (0.0–4.0)	−1.0 (−2.0 to 1.0)	−1.0 (−1.0 to −1.0)	−4.0 (−4.0 to −3.0)
- Negative Mood/Physical Symptoms	−2.0 (−4.0 to 1.0)	−1.0 (−2.0 to 1.0)	1.0 (−1.0 to 4.0)	−2.5 (−5.0 to 0.0)	−5.0 (−6.0 to −4.0)
K-MAAS (Total)[c]	−2.0 (−26.0 to 13.0)	−19.5 (−51.0 to −2.0)	−5.0 (−9.0 to −5.0)	−4.5 (−12.0 to 3.0)	21.0 (12.5–23.0)
RCMAS (Total)[c]	−1.0 (−7.0 to 2.0)	2.0 (−3.0 to 4.0)	0.0 (−3.0 to 4.0)	4.5 (−4.0 to 13.0)	1.0 (−2.0 to 4.0)
- Over worry	0.0 (−3.0 to 1.0)	0.0 (−1.0 to 3.0)	1.0 (0.0–2.0)	1.0 (−1.0 to 3.0)	−1.0 (−2.0 to −0.5)
- Sensitiveness	0.0 (−2.0 to 2.0)	0.5 (0.0–4.0)	0.0 (−1.0 to 3.0)	0.0 (−2.0 to 2.0)	−1.0 (−2.0 to −1.0)
- Body/Sleep problem	−1.0 (−2.0 to 2.0)	−1.0 (−1.0 to 0.0)	−2.0 (−4.0 to 0.0)	1.5 (1.0–2.0)	4.0 (3.0–4.0)
- Negative Emotions/Attention Problems	−1.0 (−3.0 to 1.0)	0.0 (−2.0 to 3.0)	1.0 (−2.0 to 3.0)	2.0 (−2.0 to 6.0)	0.0 (−2.0 to 1.0)
K-SCQ (Total)[c]	1.0 (−2.0 to 2.0)	−2.0 (−5.0 to 0.0)	−2.5 (−9.0 to 2.0)	4.0 (3.0–5.0)	9.0 (8.0–10.0)
K-CBCL (Total)[c]	−2.0 (−12.0 to 4.0)	−1.5 (−7.0 to 3.0)	−8.5 (−21.0 to −3.0)	−3.5 (−5.0 to −2.0)	5.0 (3.0–7.0)
- Anxiety/Depression	−3.0 (−9.0 to 15.0)	0.0 (−3.0 to 3.0)	−12.5 (−18.0 to −5.0)	−5.5 (−8.0 to −3.0)	5.0 (2.0–7.0)
- Social problems	−5.0 (−12.0 to 3.0)	−1.5 (−4.0 to 0.0)	−6.0 (−13.0 to 3.0)	−2.0 (−4.0 to 0.0)	0.0 (−2.0 to 2.0)
- Thought problems	−4.0 (−5.0 to 1.0)	−2.0 (−4.0 to 0.0)	−4.5 (−11.0 to 3.0)	−2.5 (−7.0 to 2.0)	1.0 (−1.0 to 2.0)
- Aggressive behavior	0.0 (−3.0 to 6.0)	−4.5 (−12.0 to 1.0)	−1.5 (−12.0 to 0.0)	1.5 (1.0–2.0)	11.0 (10.0–13.0)
- Internalizing problems	−5.0 (−10.0 to 8.0)	−0.5 (−4.0 to 2.0)	−11.0 (−20.0 to −1.0)	−8.5 (−16.0 to −1.0)	−1.0 (−3.0 to 2.0)
- Externalizing problems	0.0 (−11.0 to 5.0)	−2.5 (−9.0 to 3.0)	−7.5 (−18.0 to 0.0)	1.0 (0.0–2.0)	11.0 (9.0–14.0)
K-VABS-2[d]					
- Communication	(−16.0 to 14.0)	3.0 (−3.0 to 16.0)	10.5 (−35.0 to 13.0)	−3.5 (−15.0 to 8.0)	−10.5 (−14.0 to −5.0)
- Daily living skill	2.0 (−14.0 to 10.0)	−3.5 (−8.0 to 10.0)	4.0 (−35.0 to 19.0)	−3.5 (−5.0 to −2.0)	−5.5 (−9.0 to −2.0)
- Socialization	5.0 (−16.0 to 9.0)	0.5 (−3.0 to 4.0)	3.5 (−20.0 to 5.0)	12.0 (6.0–18.0)	14.0 (11.0–17.0)
Parents' measures (for parents)					
SCL-R[c]					
- Depression	−1.0 (−11.0 to 0.0)	2.0 (−10.0 to 13.0)	−1.0 (−8.0 to 5.0)	5.0 (−2.0 to 12.0)	0.0 (−3.0 to 2.5)
- Anxiety	−1.0 (−7.0 to 0.0)	0.0 (−2.0 to 11.0)	1.0 (−10.0 to 4.0)	6.5 (0.0–13.0)	2.0 (0.0–5.0)
- Obsessive compulsive personality	−6.0 (−12.0 to 6.0)	−3.0 (−6.0 to 0.0)	−4.0 (−25.0 to 12.0)	18.5 (13.0–24.0)	24.0 (19.5–28.0)
- PTSD	0.0 (−12.0 to 12.0)	2.5 (−6.0 to 27.0)	6.0 (1.0–7.0)	14.0 (5.0–23.0)	4.0 (−1.0 to 6.0)
- Anger attack	−3.0 (−14.0 to 19.0)	10.0 (−9.0 to 12.0)	0.0 (−18.0 to 3.0)	−5.5 (−11.0 to 0.0)	−8.5 (−12.0 to −5.5)
- Somatic	0.0 (−7.0 to 3.0)	2.0 (0.0–5.0)	−9.5 (−11.0 to −8.0)	8.5 (3.0–14.0)	15.0 (13.0–15.0)
- Mania	0.0 (−6.0 to 11.0)	0.0 (0.0–6.0)	−2.5 (−13.0 to 0.0)	16.5 (5.0–28.0)	22.0 (19.5–28.0)
- Paranoia	0.0 (−4.0 to 12.0)	0.0 (−3.0 to 12.0)	0.0 (−5.0 to 7.0)	9.5 (0.0–19.0)	9.5 (8.0–12.0)
- Psychosis	0.0 (−8.0 to 12.0)	−1.5 (−4.0 to 8.0)	1.0 (−4.0 to 8.0)	24.5 (0.0–49.0)	22.5 (8.0–39.0)
- Sleep disorder	−5.0 (−15.0 to 0.0)	0.0 (0.0–11.0)	−20.5 (−41.0 to 0.0)	−7.5 (−15.0 to 0.0)	5.0 (−0.5 to 10.0)
- Interpersonal sensitivity	(−15.0 to 4.0)	6.0 (−7.0 to 11.0)	−5.5 (−8.0 to 15.0)	7.5 (4.0–11.0)	4.0 (1.0–6.0)
- Regulation problem	−4.0 (−17.0 to 0.0)	2.0 (0.0–12.0)	13.0 (−8.0 to 21.0)	−4.0 (−12.0 to 4.0)	−25.0 (−29.0 to −21.0)

SRS-2: Social Responsiveness Scale-2, CDI: Children's Depression Inventory, K-MAAS: Korean version of the Mindful Attention and Awareness Scale, RCMAS: Revised Children's Manifest Anxiety Scale, K-SCQ: Korean versions of the Social Communication Questionnaire, K-CBCL: Korean Child Behavior Checklist, K-VABS-2: Korea Vineland-II, SCL-R: Symptom Checklist Revision. [a]Difference between pre and post within a group. [b]Median difference score between lower-grade (baseline and post-intervention) and higher-grade (baseline and post-intervention) groups and 95% confidence interval were estimated using 10,000 bootstrap samples. [c]Lower scores indicate increased ability. [d]Higher scores indicate increased ability.

Table 3: **Comparison of outcome variables in subgroup (Lower-grade vs Higher-grade, a version of Per Protocol).**

	Group	
	Intervention (N = 9)	Control (N = 6)
Any adverse events		
- Yes	0 (0.0%)	0 (0.0%)
- No	9 (100.0%)	6 (100.0%)

Table 4: **Summary of any adverse events during trial (Per Protocol population).**

Several previous studies have used digital techniques, such as robots, AR, and VR, to improve the social skills of children with HFASD.[30–32] Most of these digital techniques are only applied to a single child; therefore, there is no peer interaction between children. In this study, we showed the possibility of demonstrating the effect of peer-to-peer interaction, as seen in the traditional PEERS programme, using a Metaverse platform that enables children to maintain social interaction similar to offline interactions such as playing soccer at school. Furthermore, previous studies claimed that the online environment provides children with a sense of security by reducing direct exposure to contact, sounds, and violence, which makes children with HFASD feel uncomfortable.

Our study found that all indicators measured the overall social features of SRS-2 total, cognition, communication, motivation, autistic mannerism, and the primary outcome (Table 2). This is consistent with previous studies on social skills training, including PEERS, which found improvements in social awareness, cognition, communication, motivation, and autism mannerism. Moreover, we found a tendency toward CBCL anxiety and depression and social and internalising problems, which are various areas of secondary outcomes (Table 2). These findings are similar to those of previous studies on PEERS, which found improvements in social ability, interaction quality, and depressive symptoms in adolescents who received the intervention.[9,33] This result suggests that the group intervention for sociality had a potential effect on children's social competency and could also have an impact on improving friendship. Previous studies that applied online[34] and offline[9] social skills training programmes have observed a therapeutic effect on adaptive behavior; however, we did not observe an intervention effect on adaptive behavior. It is believed that this is because our intervention period was four weeks shorter than that in previous studies.

Additionally, we observed potential improvements in the anxiety, somatic symptoms, and sleep disorders of the participating caregiver (Table 2). Parental or guardian reporting is an important factor to consider as a measure of clinical outcomes, as acceptance of treatment suggests expectations for treatment efficacy.[35] These results suggest that although the programme was not directly applied to parents, improvements in the measures of the children who received the intervention can serve as an indicator of the effectiveness on the mental health of the parents/guardians.

In our study, when the intervention group was divided into lower- and higher-grades, items related to children's mental health, such as CDI (total), negative mood and physical symptoms, RCMAS (total), and negative emotions and attention, were found to have better intervention effects in the higher-grade group (Table 3). In the case of the higher-grade group, the figures were higher in the indicators of SRS (total), social awareness, motivation, autistic mannerism, K-CBCL (total), anxiety and depression, somatisation, social problems, inattention, and internalising problems than those in the lower-grade group (Table 3). Indicators that were higher in the higher-grade group were directly related to children's sociality. This suggests that the effectiveness of the social improvement programme varies depending on children's developmental stage and age, and further studies are required to determine the secondary effect of the social improvement programme according to children's chronological age. However, based on the nature of our study, it should be noted that the following conclusions should be considered as exploratory analysis and not definitive statements of effect, as our study had a relatively short duration. Therefore, making definitive conclusions regarding the observed effects is not possible.

A metaverse-based social skills training programme for children with HFASD demonstrated the potential to overcome the limitations of offline training programmes and realise the benefits of digital interventions.[36] In particular, there are reports that an imbalance in extracurricular activities other than education causes children to lack interpersonal interactions and delays language and social development.[36,37] Therefore, it is expected that a metaverse-based social skills training programme has the potential to help not only children with developmental difficulties who have difficulty accessing interventions, but also the general child population for age-appropriate development.

This study had several limitations. First, only boys were recruited for the study; therefore, an intervention effect on girls was not observed. This limitation is caused by the higher prevalence of ASD in men than in women in Korea.[38] However, in future studies, when recruiting women, the gender balance should also be considered. Second, technical issues were encountered during the data collection and analysis phases. The original plan to collect biometric data via web cameras and wearable devices failed because of data storage problems. As a result, time information from the web camera data was not obtained, preventing a more thorough analysis. To improve the methodology, future research should be established and address data storage procedures related to biometric data collection. Third, we initially planned to recruit 12 children per group;

therefore, we initially recruited 30 children, but only 20 children met our inclusion criteria. We started the study with a total of 20 children because delaying the recruitment of additional children would have resulted in longer wait times for the already recruited children, potentially leading to dropouts and depriving them of the opportunity to receive treatment. We conducted the programme for two groups, an intervention group and a control group. It was not clear whether the effect of our study was due to the contents of the PEERS programme or the application of the PEERS programme to the metaverse environment. Fourth, the sample size was small;, therefore, while this study aimed to investigate the validity of the new metaverse-based social skill training programme, and we saw its feasibility, it is difficult to generalise our results. A follow-up study is required to generalise the intervention effect by increasing the number of participating children and to evaluate whether the metaverse programme provides additional benefits in addition to traditional treatment by adding a treatment-as-usual group.

To the best of our knowledge, this is the first pilot randomised controlled trial to demonstrate a metaverse-based social skills training programme for children with HFASD. The results of this study suggest that teaching real-life social situations using the metaverse, such as playing soccer in a classroom at school, can help improve social skills and reduce emotional and behavioural problems in children with HFASD. The results of this study indicate that effective social improvement interventions can be received at home and that they could potentially be extended and applied to target groups that have difficulty in interacting with peers offline because of chronic diseases.

Contributors

YRP is the chief investigator responsible for the study design and execution and has the decision to submit the results for publication. The study design was developed and approved by JHL, TSL, SWL, JHJ, SYY, and YJC. JHL and TSL wrote the manuscript with approval from all authors and developed the statistical analysis plan. TSL, SWL, and JHJ designed and wrote the delivery and design of the therapy. SSY and YJC ensured that the investigation was conducted in accordance with the Institutional Review Board (IRB) approval and plan. YRP, JHL, TSL and SWL accessed and verified the underlying data. All authors critically reviewed the manuscript for important intellectual content and read and approved the final manuscript.

Data sharing statement

The datasets generated and/or analysed during the current study are not publicly available due to concerns about the sensitive information and the potential risk of identifying participants. However, qualified researchers may request access to the data through a formal request process, which requires ethics approval. Requests for data access should be sent to the corresponding author and will be considered on a case-by-case basis.

Declaration of interests

We declare no competing interests.

Acknowledgments

This work was supported by the Institute of Information & communications Technology Planning & Evaluation (IITP) grant funded by the Korean government (MSIT) (No. 2022-0-00234, Development of digital therapeutics (DTx) on social interaction skills of patients with Autism Spectrum Disorder).

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2023.102072.

References

1 Svenaeus F. Diagnosing mental disorders and saving the normal. *Med Health Care Philos*. 2014;17:241–244.
2 Baxter AJ, Brugha TS, Erskine HE, Scheurer RW, Vos T, Scott JG. The epidemiology and global burden of autism spectrum disorders. *Psychol Med*. 2015;45:601–613.
3 Bauminger N, Kasari C. Loneliness and friendship in high-functioning children with autism. *Child Dev*. 2000;71:447–456.
4 Eaves LC, Ho HH. Young adult outcome of autism spectrum disorders. *J Autism Dev Disord*. 2008;38:739–747.
5 Lord C, Brugha TS, Charman T, et al. Autism spectrum disorder. *Nat Rev Dis Prim*. 2020;6:5.
6 Alberto P, Troutman AC, Axe JB. *Applied behavior analysis for teachers*. Saddle River, NJ: Pearson Merrill Prentice Hall Upper; 2006.
7 Cooper JO, Heron TE, Heward WL. *Applied behavior analysis*. 2007.
8 Fountain C, Winter AS, Bearman PS. Six developmental trajectories characterize children with autism. *Pediatrics*. 2012;129:e1112–e1120.
9 Yoo HJ, Bahn G, Cho IH, et al. A randomized controlled trial of the Korean version of the PEERS® parent-assisted social skills training program for teens with ASD. *Autism Res*. 2014;7:145–161.
10 Laugeson EA, Gantman A, Kapp SK, Orenski K, Ellingsen R. A randomized controlled trial to improve social skills in young adults with autism spectrum disorder: the UCLA PEERS® program. *J Autism Dev Disord*. 2015;45:3978–3989.
11 Elder JH, Brasher S, Alexander B. Identifying the barriers to early diagnosis and treatment in underserved individuals with autism spectrum disorders (ASD) and their families: a qualitative study. *Issues Ment Health Nurs*. 2016;37:412–420.
12 Liu G, Wang S, Liao J, et al. The efficacy of wechat-based parenting training on the psychological well-being of mothers with children with autism during the COVID-19 pandemic: quasi-experimental study. *JMIR Ment Health*. 2021;8. https://doi.org/10.2196/23917.
13 Hollis C, Falconer CJ, Martin JL, et al. Annual Research Review: digital health interventions for children and young people with mental health problems - a systematic and meta-review. *JCPP (J Child Psychol Psychiatry)*. 2017;58:474–503.
14 Chengoden R, Victor N, Huynh-The T, et al. Metaverse for healthcare: a survey on potential applications, challenges and future directions. *IEEE Access*. 2023;11:12765–12795.
15 Hal K. What is the metaverse, really?. https://builtin.com/media-gaming/what-is-metaverse; 2022 [published online Oct].
16 Ringland KE, Wolf CT, Dombrowski L, Hayes GR. *Making"Safe": community-centered practices in a virtual World Dedicated to children with Autism*. Association for Computing Machinery (ACM); 2015:1788–1800.
17 Spiel K, Frauenberger C, Keyes OS, Fitzpatrick G. Agency of autistic children in technology research - a critical literature review. *ACM Trans Comput Hum Interact*. 2019;26. https://doi.org/10.1145/3344919.
18 Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016:i5239.
19 Lee J, Lee TS, Lee S, et al. Development and application of a metaverse-based social skills training program for children with autism spectrum disorder to improve social interaction: protocol for a randomized controlled trial. *JMIR Res Protoc*. 2022;11:e35960.
20 Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res*. 2016;25:1057–1073.
21 Constantino JN, Gruber CP. *Social responsiveness scale: SRS-2*. Torrance, CA: Western psychological services; 2012:106.
22 Yoo HJ. *Korean version of social communication questionnaire (SCQ)*. Seoul: Hakjisa; 2008. https://doi.org/10.5765/jkacap.2015.26.3.197.

23 Lee HL, Oh KJ, Hong KE, Ha EH. Clinical validity study of Korean CBCL through item analysis. *J Korea Acad Child Adolesc Psychiatr*. 1991;2(1):138–149.
24 Hwang S, Kim J, Hong S, Bae S, Cho S. Standardization study of the Korean Vineland adaptive behavior scales-II (K-Vineland-II). *Kor J Clin Psychol*. 2015;34:851–876.
25 Derogatis LR. *SCL-90: administration, scoring and procedures manual-I for the r(evised) version*. Baltimore: John Hopkins University School of Medicine, Clinical Psychometrics Research Unit.; 1977.
26 Cho SC, Lee YS. Development of the Korean form of the kovacs' children's depression inventory. *J Korean Neuropsychiatr Assoc*. 1990;29(4):943–956.
27 Reynolds CR, Paget KD. National normative and reliability data for the revised children's manifest anxiety scale. *School Psych Rev*. 1983;12:324–336.
28 Kwon SJ, Kim KH. Validation of the Korean version of mindful attention awareness scale. *Korea J Health Psychol*. 2007;12(1):269–287.
29 Tripepi G, Chesnaye NC, Dekker FW, Zoccali C, Jager KJ. Intention to treat and per protocol analysis in clinical trials. *Nephrology*. 2020;25:513–517.
30 Syriopoulou-Delli CK, Gkiolnta E. Review of assistive technology in the training of children with autism spectrum disorders. *Int J Dev Disabil*. 2022;68:73–85.
31 Ke F, Moon J, Sokolikj Z. Virtual reality–based social skills training for children with autism spectrum disorder. *J Spec Educ Technol*. 2020. https://doi.org/10.1177/0162643420945603.
32 Didehbani N, Allen T, Kandalaft M, Krawczyk D, Chapman S. Virtual reality social cognition training for children with high functioning autism. *Comput Human Behav*. 2016;62:703–711.
33 Dekker V, Nauta MH, Timmerman ME, et al. Social skills group training in children with autism spectrum disorder: a randomized controlled trial. *Eur Child Adolesc Psychiatry*. 2019;28:415–424.
34 O'Farrelly C, Watt H, Babalis D, et al. A brief home-based parenting intervention to reduce behavior problems in young children: a pragmatic randomized clinical trial. *JAMA Pediatr*. 2021;175:567–576.
35 Operto FF, Pastorino GMG, Scuoppo C, et al. Adaptive behavior, emotional/behavioral problems and parental stress in children with autism spectrum disorder. *Front Neurosci*. 2021;15. https://doi.org/10.3389/fnins.2021.751465.
36 Caldwell HAT, Miller MB, Tweedie C, Zahavich JBL, Cockett E, Rehman L. The effect of an after-school physical activity program on children's cognitive, social, and emotional health during the COVID-19 pandemic in nova scotia. *Int J Environ Res Publ Health*. 2022;19:2401.
37 Ilari B, Cho E, Li J, Bautista A. Perceptions of parenting, parent-child activities and children's extracurricular activities in times of COVID-19. *J Child Fam Stud*. 2022;31:409–420.
38 Hong M, Lee SM, Park S, Yoon SJ, Kim YE, Oh IH. Prevalence and economic burden of autism spectrum disorder in South Korea using national health insurance data from 2008 to 2015. *J Autism Dev Disord*. 2020;50:333–339.