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ORIGINAL PAPER

Effect of a Focused Social and Communication Intervention on Preterm Children with ASD: A Pilot Study

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Abstract

While advances in intensive neonatal care have greatly improved survival rates among preterm infants, incidence of neurodevelopmental disorders in this group is still high, with autism spectrum disorder (ASD) being one of the most frequent. To this end, we conducted a social-communication intervention aimed at investigating efficacy in social-communicative skills. Eighteen children (preterm and full-term with ASD and preterm children) aged 18 through 20 months participated in the study. Our findings indicate that most participants in the intervention groups registered significant improvements in terms of socio-communicative skills, cognitive development, and language. Accordingly, these pilot data underscore the need for further research and implementation of early interventions in young preterm children with ASD.

Keywords Autism spectrum disorder · Preterm · Intervention · Social · Communication

Introduction

Globally, 15 million babies are born prematurely (< 37 weeks' gestation) each year (Blencowe et al., 2013). While advances in neonatal intensive care have greatly improved survival rates among premature infants (Anderson et al., 2016), this increase has nonetheless been accompanied by a worrying rise in the incidence of neurodevelopmental disorders in this group (Cheong et al., 2017). Low gestational age may increase the vulnerability of the developing brain and, along with other exposures associated with preterm birth, might act as casual pathways for autism spectrum disorder (ASD; Joseph et al., 2017). ASD is a neurodevelopmental disorder of early onset, characterized by deficits in social communication, accompanied by restricted and repetitive patterns of behavior, interests or activities which have

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significant negative consequences for daily life (American Psychological Association, 2013). A recent meta-analysis reported an ASD prevalence of 7% (range 4% through 9%) in this population, based on a total sample of 3366 preterm infants (Agrawal et al., 2018). This difference is relevant when compared to the general population, in which the overall prevalence of ASD is 1% (Lord et al., 2020).

Preterm children have an increased likelihood of ASD, and those who eventually receive an ASD diagnosis display fewer early socio communicative behaviors than do typically developing children (Mateus et al., 2020). Furthermore, they register significantly higher scores in the Autism Diagnostic Observation Schedule (Lord et al., 2000) than do preterm peers who eventually do not receive a diagnosis of ASD, thus indicating less optimally developed social and communicative skills (De Groote et al., 2006; Matheis et al., 2018). Recent studies observing infant communication skills in mother-infant interaction at 12 months found that preterm infants displayed less frequent social and communicative interaction and produced fewer pointing, giving, and representational gestures than did full-term infants (Benassi et al., 2016; Sansavini et al., 2015). This population likewise shows different early cognitive and language development trajectories (Allotey et al., 2018; Chen et al., 2020).

Early intervention programs for the ASD population, such as social and communication interventions (SCIs), have been purpose-designed to reduce ASD signs. The aim of such early interventions is to prevent the consequences of these difficulties, by initiating proactive treatment even before the child receives a formal diagnosis. In addition to being shown to improve social and communicative skills, cognitive development, language, and adaptive behavior (Bejarano-Martín et al., 2020a; Gates et al., 2017; Zwaigenbaum et al., 2015), it has also been suggested that early interventions can reduce the burden of ASD and improve the quality of life of children and their families (Bejarano-Martín, 2020b; Salomone et al., 2016; Fletcher-Watson et al., 2017). SCIs target behaviors such as imitation, joint attention (JA) and play, which have a fundamental role in developing social skills, social-emotional communicative functions, and theory of the mind, as well as language and play skills (Adamson et al., 2019; Dohmen et al., 2016; Kasari et al., 2015; Pickard & Ingersoll, 2015).

A number of SCIs have been implemented with the aim of reducing initial symptoms of ASD in children with increased likelihood of ASD before a formal diagnosis is made (Landa, 2018; Rogers & Vismara, 2014). Similarly, several early intervention programs have sought to improve different social skills (e.g., imitation, joint attention, and play) of preterm infants (e.g., Bagner et al., 2010; Chernego et al., 2018). To date, however, no early intervention program has studied its efficacy on preterm children who eventually receive a diagnosis of ASD. On the other hand, there is currently no evidence to show that this group is comparable with full-term infants with ASD, or even that the impairments of preterm infants who show characteristics of ASD can be reduced through an early intervention program.

This paper reports the results of an early-intervention pilot study aimed at ascertaining whether a focused social-communication intervention can yield broader gains in social, cognitive, language, and adaptive functioning in young preterm children with autism and its feasibility and acceptability. More specifically, our study sought to: (a) examine the effect of the social-communication intervention program on young preterm and full-term infants with ASD; (b) explore whether there were differences in intervention gains as between preterm infants with ASD, full-term children with ASD (comparison group), and another preterm infant group without increased ASD (control group); (c) investigate the individual effect of the intervention; and lastly (d) assess feasibility and acceptability of the SCI in preterm and full-term children with ASD. Moreover, this is the first study to use individual change indices in a pre-post design with preterm infants with ASD, a comparison group, and a control group.

Methods

Ethical Approval

Ethical approval was given by the Research Ethics Committee of the University of Salamanca (201700031949) and the Salamanca Clinical Hospital, Spain (PI9910/2017). Prior to starting the program, all participant families were required to read the information about the study and give their informed consent.

Design

To determine the effects of the intervention on preterm children with ASD, a quasi-experimental design was used to compare the following three groups: (1) an experimental group of preterm children with ASD and receiving an SCI; (2) a comparison group of children with ASD and receiving an SCI; and lastly, (3) a control group of preterm children. To examine individual child growth and variables affecting these outcomes, data from all subjects in each group were analyzed jointly as well as individually. Figure 1 shows the participant flow across the study.

Participants

Children were recruited from a developmental disorder diagnostic and rehabilitation centre and from the Salamanca Clinical Hospital through a developmental surveillance

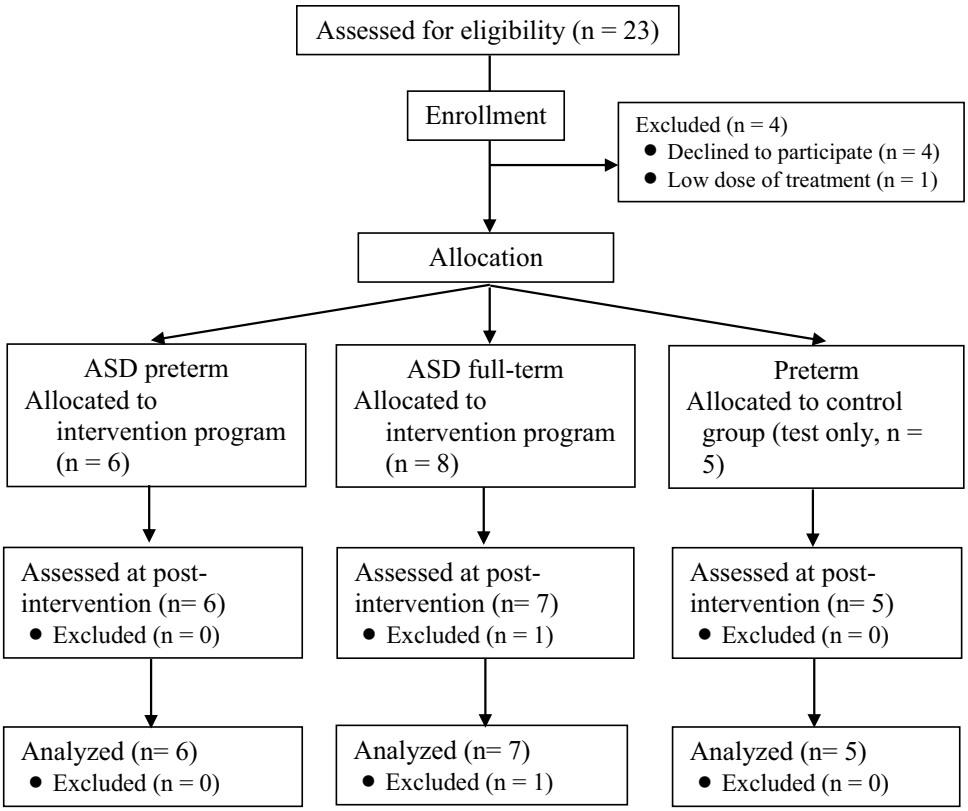

Fig. 1 Recruitment flow diagram

program (visits at 6, 12, 18 and 24 months) that was ongoing at the time of the study, and they were allocated to the three groups in accordance with the respective inclusion criteria, i.e., (1) Preterm children with ASD: (a) < 37 weeks of gestation at birth, (b) chronological age 18–20 months (corrected by subtracting gestational age at birth from 40), and (c) score above the designated cut-off level on the Autism Diagnostic Observation Scale – 2nd edition (Toddler module, Lord et al., 2012) and on the Modified Checklist for Autism in Toddlers – revised/follow-up (M-CHAT-R/F, Robins et al., 2014), deemed to show concern of ASD (ADOS ≥ 9; M-CHAT-R/F ≥ 3). (2) Full-term children with ASD: (a) chronological age 18–20 months, and (b) score above the designated cut-off level on the ADOS2 – T module and on the M-CHAT-R/F, deemed to show concern of ASD. (3) Preterm children: (a) < 37 weeks of gestation at birth, (b) chronological age 18–20 months (corrected by subtracting gestational age at birth from 40), and (c) score under the designated cut-off level on the ADOS2 – T module and on the M-CHAT-R/F, *not* deemed to show concern of ASD (ADOS < 9; M-CHAT-R/F < 3). The exclusion criteria were defined as moderate-severe hearing/visual deficits or motor disorders (e.g., cerebral palsy, epilepsy, spinal cord), or other co-morbid medical conditions. ASD diagnosis was confirmed at 24 months.

Recruitment took place over 24 months (December 2017 through November 2019). Due to this rolling enrollment process, children continued to enter the intervention throughout the treatment period. Control group (preterm children) were selected randomly from the Salamanca Clinical Hospital database. Four families declined to participate due to busy family schedules and associated medical conditions.

The final sample comprised 18 children assigned to the three groups. ASD characteristics was assessed with the ADOS2-T module by a multi-disciplinary team on the basis of a comprehensive clinical evaluation and the M-CHAT-R/F. There were no significant differences between preterm and full-term children with ASD. However, there were significant differences between the experimental and control groups in the ADOS-T module ($d = 73$), Cognitive ($d = 81$) and Language ($d = 85$) composite scores, and Communication ($d = 86$), Socialization ($d = 88$), Object Imitation ($d = 71$), Joint attention (Response; $d = 66$), and Play (Acts, $d = 67$; Frequency, $d = 70$) measures. The members of the control group did not have characteristics of ASD, and all their pre-treatment scores were higher. Table 1 below summarizes the descriptive sample information.

Measures

Coding and Reliability

For each coding system, 100% of the videos were double-coded to establish reliability statistics (intraclass correlation

Table 1 Child demographics

	Preterm ASD (n = 6)	Full-term ASD (n = 7)	Preterm (n = 5)	Preterm ASD vs. Full-term ASD	Preterm ASD vs. Preterm
	M (SD)/frequency (%)	M (SD)/frequency (%)	M (SD)/frequency (%)	$\chi 2$/F	$\chi 2$/F
Gender					
Male	5 (83%)	7 (100%)	4 (80%)	$\chi 2 = 0.48$	
Female	1 (17%)	0 (0%)	1 (20%)		
Chronological age[+]	19.17 (0.41)	20.00 (1.15)	18.60 (0.89)	0.279	0.219
Gestation at birth (weeks)	31.67 (4.88)	–	30.80 (2.77)	–	0.597
ADOS2-T	16.33 (3.45)	15.86 (3.49)	0.86 (0.71)	0.50	12.16*
Cognitive[a]	70.50 (9.53)	71.71 (7.61)	93.00 (5.70)	− 2.05	− 23.58*
Language[a]	63.00 (8.50)	59.71 (6.85)	88.00 (5.29)	0.50	− 28.17*
Communication[b]	70.17 (8.23)	66.86 (5.79)	94.60 (2.70)	2.75	− 17.58**
Socialization[b]	79.17 (7.58)	77.14 (5.04)	91.20 (6.46)	0.75	− 8.23
Object imitation	5.83 (4.17)	5.71 (3.55)	14.60 (1.14)	− 1.30	− 8.87*
JA initiation	0.33 (0.52)	1.29 (1.50)	4.80 (0.84)	− 0.75	− 4.41*
JA response	4.83 (1.94)	3.57 (2.64)	6.60 (0.89)	1.20	− 1.33
Play					
Acts	4.67 (2.58)	4.93 (2.45)	9.25 (2.02)	− 1.20	− 5.53*
Frequency	12.57 (1.75)	11.95 (2.96)	18.64 (1.53)	− 0.54	− 7.12*
Parents' highest level of education					
Secondary school or less	1 (17%)	1 (14%)	1 (20%)	$\chi 2 = 0.98$	
High school	1 (17%)	2 (29%)	1 (20%)		
Graduate	4 (66%)	4 (57%)	3 (60%)		
Treatment received (hour)	29.10 (1.53)	29.23 (1.76)	–	− 0.62	–
Treatment as usual received (hour)	8.00 (4.90)	9.14 (3.02)	8.60 (3.29)	− 1.17	− 1.02

JA Joint attention; $\chi 2$ Chi-square

[+]Corrected for preterm children (subtracting gestational age at birth from 40)

*$p < 0.05$, **$p < 0.001$

[a]Composite Score in Bayley-III

[b]Standard Score in Vineland-II

coefficients (ICCs) and Kappa coefficients), which are reported for all coding systems except parents' measures. The mean between pre- and post-treatment measures was calculated, as were the ICCs using the formula of a two-way mixed effects model, with absolute agreement and single rater/measurement (Koo & Li, 2016). Assessments were videotaped and all tests were scored from the video, except for the M-CHAT/R and Vineland-III due to the fact that these tools are based on questions that parents must answer. Research assistants were purpose-trained to code the videotaped measures reliably. Videos were distributed to independent coders. Research assistants were blind to the study hypothesis, treatment condition, and time points.

Feasibility and Acceptability

A mixed methods approach was adopted to establish feasibility and acceptability. As such, we collected data on feasibility and acceptability as outlined below.

Feasibility was assessed by collecting data on recruitment and retention rates, adherence rates, time required to recruit, and attrition. Lastly, feasibility of testing procedures and data collection methods, including completion rates.

Acceptability of the intervention and study procedures was assessed both quantitatively and qualitatively. Quantitative data was collected to investigate the number of sessions attended and length of intervention. A survey was designed to collect parents' views and experiences of the intervention, including what they perceive to be barriers and facilitators. Families were asked to report the degree of adequacy of the service on a scale of 1 to 6 (1: extremely inadequate; 2: moderately inadequate; 3: slightly inadequate;

4: neither adequate nor inadequate; 5: slightly adequate; 6: moderately adequate; 7: extremely adequate). The different answer choices for these questions were then collapsed and recoded into three categories, namely, Inadequate (from 1 to 3), Neutral (4) and Adequate (from 5 to 7), for the purpose of conducting a comparative analysis. Families were asked to rate the agreement in the following variables: information and support received, the evaluation process and recruitment, participation in sessions, the number of sessions, the length of intervention, the setting of the intervention, the delay between recruitment and start of intervention, staff qualifications, and the level in which professionals took into account family's concerns (see Table 2 in the Results section).

Primary Outcome Measures

The effect of the intervention on imitation, joint attention and play skills was examined using three assessments scored by trained research assistants blind to the participants' group assignment.

The Unstructured Imitation Assessment tool (UIA; Ingersoll, 2010) was used to measure children's ability to imitate in a spontaneous, social-interactive context. The UIA consists of 10 object- and 10 gesture-imitation tasks, but the gesture-imitation task was eliminated due to the age of the participants. The examiner engaged the child in free play with a set of toys, and then alternated between imitating of the child's nonverbal behavior and modeling actions for the child to imitate (e.g., roll a ball on a Table 3 times saying 'roll, roll, roll'). The child's response was scored '0' for no response or an incorrect response, '1' for an emerging response, and '2' for a full imitative response. Scores could range from 0–40, with a Kappa value of 0.92.

The Joint Attention Protocol (JAP, Nowell et al., 2018) was used to measure a child's response to initiation bids and his/her own initiation bids during a semi-structured interaction with the examiner. The protocol alternates between eight initiation trials and eight response trials, providing a total of 16 opportunities to observe joint attention. Response to JA tasks increases in level of support and prompting gradually across the assessment. All items were scored dichotomously as follows: '1' for pass or '0' for fail. Kappa scores were 0.95 for JA Response and 0.94 for JA Initiation measures.

The Structured Play Assessment instrument (SPA; Ungerer & Sigman, 1981) was used to measure the frequency and acts of spontaneous play behaviors. The child is presented with five sets of toys at a table. The examiner may respond to the child's communication but may not direct the child's play or show the child how to play with the toys. The play interaction lasted approximately 15–20 min. The variables used in the analysis were Simple object (e.g., separate objects, mouthing objects), Combination (e.g., nesting cups), Presymbolic (e.g., object used in a way that indicates a pretend quality), and Symbolic play (e.g., object used to represent another, doll used as a play agent). Simple object and Combination play, and Presymbolic and Symbolic play were collapsed into two categories (Manipulative – Pre/Symbolic), by summing the scores. The ICCs were as follows: for (1) Play Acts, they were 0.93 for Simple object, 0.91 for Combination, 0.89 for Functional, and 0.90 for Symbolic play; and for (2) Play frequency, they were 0.87 for Simple object, 0.86 for Combination, 0.88 for Functional, and 0.85 for Symbolic play.

Secondary Outcome Measures

The Ados2 T-Module and M-CHAT-R/F were used as screener tests to measure the risk for ASD. The Toddler Module algorithm contains separate domain categories of Social Affect (SA) and Restricted, Repetitive Behaviors (RRB) and a single total score to determine classification.

Table 2 Percentage of satisfaction among parents according to the intervention group

	Preterm children with ASD parents (n = 6)			Full-term children with ASD parents (n = 7)		
	Inadequate	Neutral	Adequate	Inadequate	Neutral	Adequate
Information and support received	0	0	100	0	14.3	85.7
The evaluation process and recruitment	0	0	100	0	0	100
Participation in sessions	0	0	100	0	0	100
Number of sessions	16.7	0	83.3	0	14.3	85.7
Length of intervention	0	0	100	0	0	100
Setting of intervention	0	16.7	83.3	0	0	100
Delay between recruitment and start of intervention	0	0	100	0	0	100
Staff qualifications	0	0	100	0	0	100
Professionals took into account family's concerns	0	0	100	14.3	0	85.7

Table 3 Means and standard deviations of pre- and post-intervention measures for all three groups of children

Test	Preterm with ASD						Full-term with ASD						Preterm					
	Pre-test Mean (SD)	Post-test Mean (SD)	t	CI (95%) Low	CI (95%) Up	Cohen's *d*	Pre-test Mean (SD)	Post-test Mean (SD)	t	CI (95%) Low	CI (95%) Up	Cohen's *d*	Pre-test Mean (SD)	Post-test Mean (SD)	t	CI (95%) Low	CI (95%) Up	Cohen's *d*
Object imitation	5.83 (4.17)	13.83 (3.49)	− 4.30*	− 16.09	− 2.40	0.95	5.71 (3.55)	13.57 (3.60)	− 7.72*	− 10.87	− 5.12	0.88	14.60 (1.14)	16.00 (0.71)	− 2.98	− 3.26	− 0.59	0.60
JA initiation	0.33 (0.52)	3.33 (0.82)	− 6.69*	− 4.79	− 1.70	0.86	1.29 (1.50)	2.86 (1.77)	− 2.32	− 4.39	0.39	0.54	4.80 (0.84)	5.80 (0.45)	− 2.98	− 3.25	0.59	0.60
JA response	4.83 (1.94)	6.83 (1.33)	− 2.65*	− 4.40	0.40	0.74	3.57 (2.64)	5.14 (2.54)	− 1.44	− 5.24	1.64	0.33	6.60 (0.89)	7.60 (0.55)	− 1.95	− 4.27	1.60	0.69
Play acts manipulative	3.00 (0.92)	2.92 (0.77)	0.51	− 2.59	3.59	0.25	3.00 (1.53)	1.43 (0.78)	1.83	− 0.72	3.52	0.52	2.00 (0.71)	1.73 (0.65)	1.49	− 1.26	2.59	0.58
Play Freq. manipulative	21.33 (3.83)	11.33 (3.27)	− 0.05	− 16.16	15.66	0.02	15.86 (7.15)	5.86 (2.80)	2.20	− 3.22	28.02	0.72	11.20 (0.84)	6.20 (1.30)	1.05	− 5.18	8.51	0.32
Play acts Pre/Symbolic	1.67 (1.63)	4.67 (2.34)	− 7.35*	− 4.30	− 1.70	0.70	3.14 (1.95)	6.14 (2.91)	− 4.49*	− 3.88	− 0.91	0.68	5.40 (1.57)	6.40 (1.14)	− 1.97	− 3.27	− 0.77	0.46
Play Freq. Pre/Symbolic	3.83 (3.71)	14.00 (6.66)	− 4.94*	− 17.68	− 3.82	0.84	8.71 (6.10)	18.43 (7.12)	− 6.39*	− 12.91	− 5.08	0.96	14.40 (2.07)	18.00 (1.87)	− 2.25	− 9.72	3.05	0.52
Cognitive[a]	70.50 (9.53)	85.83 (8.01)	− 2.58	− 31.22	3.22	0.64	71.71 (7.61)	83.57 (8.06)	− 2.47	− 27.98	1.58	0.64	93.00 (5.70)	96.00 (5.48)	− 0.74	− 11.28	7.95	0.31
Language[a]	63.00 (8.50)	71.50 (9.94)	− 6.55*	− 15.60	− 5.39	0.44	59.71 (6.85)	70.29 (9.53)	− 7.03*	− 13.11	− 5.69	0.60	88.00 (5.29)	90.00 (3.54)	− 2.13	− 7.04	2.38	0.41
Communication[b]	70.17 (2.71)	78.17 (2.64)	− 22.50**	− 8.56	− 6.43	0.96	66.86 (5.79)	75.00 (5.41)	− 28.69**	− 9.21	− 7.58	0.97	94.60 (2.70)	96.20 (3.12)	− 1.73	− 3.48	1.48	0.26
Socialization[b]	79.17 (3.82)	82.17 (5.15)	− 2.61	− 7.76	0.76	0.65	77.14 (5.04)	81.86 (6.04)	− 3.26*	− 7.40	− 0.60	0.48	93.00 (3.16)	91.20 (6.46)	− 0.19	− 7.61	6.95	0.08

JA Joint attention

*$p < 0.05$, **$p < 0.001$

[a]Composite Score in Bayley-III

[b]Standard Score in Vineland-III

Clinical cut-off scores are grouped within levels of concern for ASD (risk for ASD SA + RBB > 9). In the M-CHAT-R/F parents answer 20 yes/no questions; if children screen positive, parents are asked structured follow-up questions to obtain additional information and examples of at-risk behaviours (risk for ASD a score ≥ 3).

The Bayley Scales of Development – 3rd edition (Bayley, 2006) was used to measure cognitive development and language. The ICCs were as follows: 0.94 for Cognitive scalar score; 0.92 for Age development; 0.97 for Language scalar score; 0.95 for Age receptive; and 0.97 for Age expressive.

The Vineland Adaptive Behaviour Scales, 3rd edition (Sparrow et al., 2016) was used to measure the Communication and Socialization domains. The scales are organized by reference to the three domains that correspond to the three broad domains of adaptive functioning specified in the DSM-5 (APA, 2013). The Parent/Caregiver form was used.

Assessment Procedure

Pre- and post-tests were administered at the children's treatment centre by one of two independent testers. The age of preterm children was corrected in pre- and post-treatment (by subtracting gestational age at birth from 40). The assessment started with the ADOS, followed by the Bayley-III; after a 30-min break, the UIA, JAP and SPA were then administered, in that order. Parents completed the M-CHAT-R/F and Vineland-III. Parents were also asked about the background characteristics of the child and family members, and specifically about the child's health history, as well as any additional interventions received before and during the study. Parents were allowed in the testing room during the assessment and the assessment took approximately 180 min. The time between pre- and post-assessment was four months. ASD diagnosis was confirmed at post-treatment time.

Intervention Procedure

Intervention Groups

All therapy was conducted by a graduate-level research assistant coached in the treatment model by trained interventionists (established fidelity of > 0.80 prior to commencement of and during treatment). Children in treatment groups (preterm and full term with ASD) received an SIC which targeted object imitation, joint attention and play one h per day, two days per week for 15 weeks (30 h). All sessions were conducted in a small treatment room, with a small table and chairs placed in the centre. Parents were allowed to be present during the intervention sessions. Fifteen sets of play materials were used in all treatment sessions. The program followed the principles of the treatment program developed by Ingersoll and Dvortcsak (2009, 2019): (Improving Parents as Communication teachers, Project ImPACT). Challenging behavior chapter was eliminated due to the focus of the study (social and communication skills). This program was chosen because is recognized as one of the most effective programs for children with ASD and related social communication delays. This intervention teaches strategies to help children develop social, communication, imitation, and play skills during daily routines and activities from 18 months of age. Therefore, the program is supported by research and based on developmental science and applied behavioral analysis (ABA) principles. It was recently recognized as a Manualized Intervention Meeting Criteria by the National Clearinghouse on Autism Evidence and Practice (NCAEP).

The SIC used naturalistic and behavioral techniques to teach social-communication skills during play and daily life activities (e.g., snack time). The therapist focused on children by following their lead and imitating them, adjusting the communication, creating opportunities, and teaching new skills. To follow the child's lead, the therapist stayed face-to-face with children, letting them choose and lead the play game or activity. Thereafter, the therapist joined in the child's play. To promote reciprocity, the therapist imitated the child's verbal and nonverbal behavior, adjusting the communication to the child's level. Both verbal and non-verbal communication were exaggerated, and a simple and repetitive language was used around the child's play. Communication opportunities were created, based on turns and toys placed in different containers or out of the child's reach.

Lastly, prompts and rewards to teach new skills were used. To teach object imitation the therapist modelled an action for the child to imitate. If the child did not learn the action within three models, the therapist used physical guidance. The actions were modelled with the duplicate of the toy with which the child was currently playing. The therapist taught responses to joint attention by pointing to different child's favourite toys. The initiations of joint attention were taught throughout exaggeration each time the child show or give something to the therapist. To expand play, the therapist used a verbal instruction or modelled an action for the child to imitate. If the child did not learn the action (imitation, joint attention, play) within three models or prompts, the therapist used physical guidance. Modelled and prompted actions were varied across toys to help children generalize behaviours avoiding associate a specific skill with a specific toy. Therapist rewarded children after attempts that met criteria at social-communication skills. The rewards were natural, and therapist gave them only for positive behaviours, and immediately.

Families were not barred from receiving other community services alongside the SCI, and documented other community services received by the two groups. Community treatment consisted of early stimulation sessions aimed at developing motor and cognitive skills.

Control Group

The preterm children participated in all assessment activities, but no SCI was administered during the study. Instead they received treatment-as-usual within their community settings. The control group did not present with ASD symptoms and thus received no SCI. There were no differences between the groups in terms of the number of hours of community services received (Table 1).

Data-Analysis

Statistical analyses were performed, using the IBM SPSS Statistics 26 and R Development Core Team software packages in the following ways: (1) analyses of intervention, determining the feasibility and acceptability; (2) analyses by group, determining the significance and effect of the intervention in each group, and comparing groups; (3) analyses by participant, determining the significance and effect of the intervention on each participant.

Firstly, comprehensive descriptive analyses of the two intervention groups (preterm and full-term with ASD parents) were performed related to feasibility and acceptability of treatment and identifying barriers and enabling factors to completion of the program. The categories of the assessment of the acceptability with intervention was a scale of 1 to 7 (1: extremely inadequate; 2: moderately inadequate; 3: slightly inadequate; 4: neither adequate nor inadequate; 5: slightly adequate; 6: moderately adequate; 7: extremely adequate). The different answer choices for all questions were then stratified and recoded into three new categories, namely, inadequate (from 1 to 3), neutral (4) and adequate (from 5 to 7).

Secondly, robust statistical analyses were conducted to control the range of probability distributions, especially in the case of small samples or distributions that were not normal (Daszykowski et al., 2007). To ascertain whether the groups differed in background variables, chi-square tests and robust analyses of variance (ANOVA) were performed. Robust paired-sample t-tests were used to determine the significance and effect of the intervention on pre- and post-treatment variables in each group. Additionally, robust ANOVA were performed to determine whether the groups differed in terms of Change Score (CS = post – pre score). Post-hoc analyses were conducted where significant differences were found between groups. Cohen's *d* was used to calculate the effect size (small < 0.20; medium ≥ 0.50; large ≥ 0.80).

Lastly, the Reliable Change Index (RCI, Jacobson et al., 1984) was calculated to determine whether the individual change in the different measures was reliable. Of the different RCI versions available, we used one in which the equality of pre- and post-test variances was not assumed (Christensen & Mendoza, 1986; Jacobson & Truax, 1991; Maasen, 2004). Reliability was estimated from the pre-post correlation (Estrada et al., 2019; Ferrer & Pardo, 2014) as follows:

$$RCI = \frac{Di}{\sqrt{(Spre\sqrt{1 - Rpre - post})^2 + (Spost\sqrt{1 - Rpre - post})^2}}$$

where Di = individual pre-post difference, $Spre$ = standard deviation pre-test, $Spost$ = standard deviation post-test, and $Rpre\text{-}post$ = pre-post correlation. This formula was computed for each participant in all measures, with individual changes being deemed reliable in any case where the RCI was higher than 1.96 ($p < 0.05$). The individual pre-post difference (Di) was calculated on the basis of the measure used to obtain a comparable RCI (≥ 0), namely: (1) 'Pre – Post' in measures aimed at reducing the pre-treatment score (e.g., Ados2—T module); and, (2) 'Post – Pre' in measures aimed at increasing the pre-treatment score (e.g., Object Imitation, Cognitive development).

Results

Feasibility and Acceptability

Twenty-seven children were assessed for eligibility. The time to recruit children was 180 min, where the complete assessment was administrated. The 14.8% of children were excluded before starting the program. In one case the reason for exclusion was that the child had associated health complications. In the remaining cases the reason for exclusion was that parents refused to participate due to busy schedules or medical associations. Fourteen children in both groups (preterm and full-term children with ASD) were allocated to intervention program. Only one child (7.1%) was excluded due to the low dose of treatment. The family refused to continue with the program when the child had received only eight hours because of the distance with the service and the lack of transport. All children completed pre- and post-treatment assessment (primary and secondary measures).

Children in the intervention groups completed almost all the sessions. Preterm children with ASD received 29.1 h (97.1% of the program), and full-term children with ASD received 29.2 h (97.3% of the program). Children in both groups attended at 98% of the programmed sessions. Parents reported high level of satisfaction with the intervention program. Between 83 and 100% reported that the program was adequate throughout all the variables (See Table 2). Parents of preterm children with ASD reported that medical appointment was a barrier to attend to some intervention sessions.

Intervention Effects

As shown in Table 3, the SCI had a statistically significant effect on most measures of the preterm and full-term ASD risk groups. The effect size was large (d > 0.80) in the same measurements for both groups. In pre-post JA Initiation and JA Response, preterm participants with ASD obtained a higher and significant effect. Significance was higher in both groups in pre-post Communication scores. No significant pre-post effect was observed in the preterm group.

Figure 2 shows the mean pre-post treatment scores for each group. While pre-treatment differences were higher between the intervention and control groups, these differences diminished post-treatment; and although the intervention groups obtained lower scores before starting treatment, the differences were significantly reduced after treatment. Control group scores remained stable over time.

Change Score between Groups

Change Scores were used to control for pre-treatment differences. Despite the fact that the pre-post treatment effect was lower in the intervention groups for most of the measures assessed, statistically significant inter-group differences were solely found in the Change Scores for the Object Imitation, Play Acts Pre/Symbolic, and Language measures (Table 4). The differences were greater in Object Imitation ($F = 27.60$, $p < 0.001$) and Communication ($F = 72.50$, $p < 0.001$). Preterm and full-term ASD risk groups obtained a significantly higher CS. As can be seen in Fig. 2, these differences were

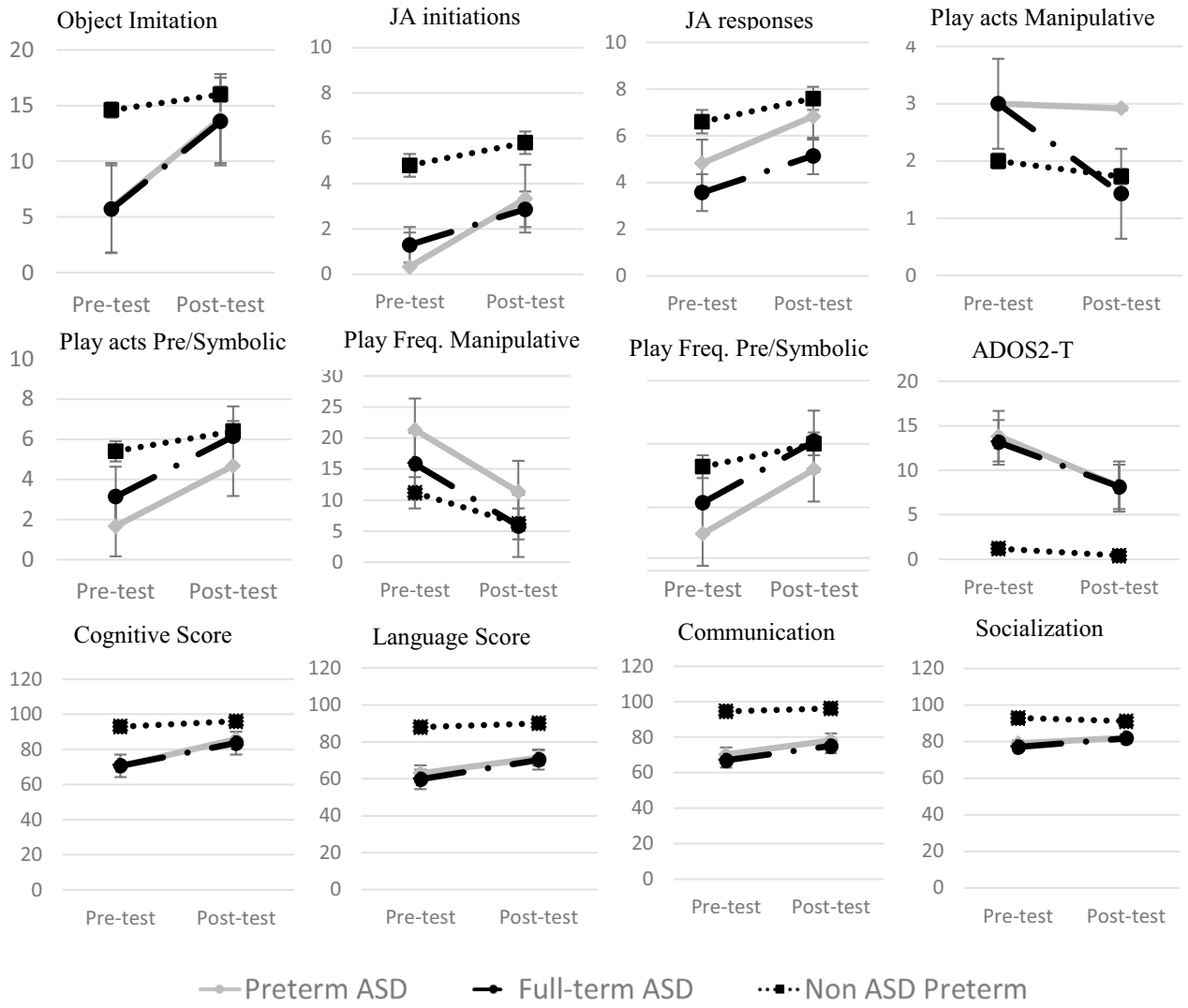

Fig. 2 Pre-post treatment means of each measure by group. Errors bars represent standard error

Table 4 Change score group differences

Test	Differences	Post-hoc analyses								
	F	Preterm with ASD vs. Full-term with ASD			Preterm with ASD vs. Preterm			Full-term with ASD vs. Preterm		
		psi-hat	CI (95%)		psi-hat	CI (95%)		psi-hat	CI (95%)	
			Low	Up		Low	Up		Low	Up
Object imitation	27.60**	− 0.30	− 6.75	6.15	5.83**	− 0.93	12.60	6.13**	3.51	8.75
JA initiation	4.17	–	–	–	–	–	–	–	–	–
JA response	0.89	–	–	–	–	–	–	–	–	–
Play acts manipulative	2.05	–	–	–	–	–	–	–	–	–
Play Freq. manipulative	3.08	–	–	–	–	–	–	–	–	–
Play acts Pre/Symbolic	11.3*	0.45	− 2.27	3.17	2.25*	0.83	3.67	1.80	− 0.91	4.51
Play Freq. Pre/Symbolic	3.21	–	–	–	–	–	–	–	–	–
Cognitive[a]	3.97	–	–	–	–	–	–	–	–	–
Language[a]	12.2*	− 1.10	− 6.27	4.07	5.50*	0.51	10.49	6.60*	2.04	11.15
Communication[b]	72.50**	− 0.40	− 2.69	1.89	6.33**	3.85	8.81	6.73**	4.66	8.81
Socialization[b]	2.69	–	–	–	–	–	–	–	–	–

JA Joint attention

*$p < 0.05$, **$p < 0.001$

[a]Composite Score in Bayley-III

[b]Standard Score in Vineland-III

larger pre-treatment and decreased post-treatment. No statistically significant differences were found between preterm and full-term ASD risk groups.

Reliable Change Index

The preterm and full-term ASD risk groups registered a significant, reliable mean change in the same measures (Table 5). In both groups, participants' mean RCI was significant (> 1.96) for the Object Imitation, Play Acts and Frequency Pre/Symbolic, Language, and Communication measures. Most participants obtained a significant RCI in these measures, with 4 to 6 (57% − 85%) participants in both groups achieving a reliable change (> 1.96). No significant RCIs were found in the preterm group. Individually, only one participant obtained a significant RCI in Play Frequency Pre/Symbolic (see Fig. 3 for fuller details of participants who obtained a significant RCI in each group).

Discussion

This pilot study examined the effect of an SCI on social and communicative functioning, cognitive development, and language in young preterm and full-term children with ASD. Children in the intervention groups made significantly greater pre-post-treatment gains in Object Imitation, Play, Language and Communication than did the control group. Furthermore, there were no differences between preterm and full-term children with ASD in any domain, with individual RCI analyses supporting the results obtained in group analyses. Although there was a significant change in specific social and communication skills, the results should be taken cautiously. The present study is a pilot study and was limited by its small sample size.

These findings are similar to those reported by other studies aimed at improving social and communication skills in young children with ASD (Landa, 2018; Rogers & Vismara, 2014). Although the developmental trajectory studied was short (from pre- to post-treatment, 5 months), the trajectory of preterm children with ASD was close to the trajectory of the control group, post-treatment. This finding may suggest that it was the early intervention rather than simple maturation which enhanced these skills (Marsden & Torgerson, 2012). Preterm children with ASD tend to show impairments in their social and communication, cognitive or language developmental trajectories, with these trajectories moving downwards over time and thereby increasing the difference with other preterm children (Chen et al., 2020; Nguyen et al., 2018). This is the first pilot study of an early intervention program in preterm children with ASD. Since this is a group with a high prevalence of ASD (7%; Agrawal et al., 2018), future research should focus on the study of the early intervention programs which produce better results.

Comparison of both groups with ASD (preterm and full-term) seemed to show no differences. Likewise, no

Table 5 Reliable change index with R correlation

	Preterm with ASD						*M*	Full-term with ASD							*M*	Preterm					*M*
Test	1	2	3	4	5	6		1	2	3	4	5	6	7		1	2	3	4	5	
Object imitation	2.03	4.74	2.37	1.35	3.72	2.03	2.71*	3.05	2.71	4.06	2.71	2.71	1.35	2.03	2.66*	1.02	1.35	1.35	0.68	1.35	1.15
JA initiation	1.90	1.90	1.27	2.54	2.54	1.27	1.90	0.00	− 0.63	3.17	0.00	1.27	1.90	1.27	0.99	0.63	1.27	0.00	0.63	0.63	0.63
JA response	1.93	2.57	0.00	0.64	1.29	1.29	1.29	3.86	0.00	1.29	0.64	0.00	0.64	0.64	1.01	0.00	1.29	1.29	0.00	0.64	0.64
Play acts manipulative	0.67	0.00	1.34	0.67	0.67	1.34	0.11	1.34	1.34	2.01	− 0.67	0.67	0.67	2.01	1.05	0.67	0.00	2.01	0.67	0.67	0.53
Play Freq. manipulative	− 1.16	0.25	− 0.25	0.31	0.12	0.31	− 0.07	− 0.49	2.33	1.23	0.12	0.74	0.80	1.04	0.82	0.37	0.00	− 0.06	0.06	0.12	0.07
Play acts Pre/Symbolic	3.52	3.52	2.64	2.64	2.64	0.88	2.64*	1.76	3.52	5.28	0.88	2.64	0.88	3.52	2.64*	0.88	0.88	0.00	1.76	0.88	0.88
Play Freq. Pre/Symbolic	4.29	4.29	1.65	3.30	2.97	1.98	3.08*	3.30	4.95	4.29	1.98	3.63	1.98	2.31	3.20*	1.98	0.66	0.66	1.98	0.66	1.18
Cognitive[a]	2.28	1.37	0.09	0.91	2.83	0.91	1.40	− 0.91	0.91	3.01	0.55	1.10	1.55	1.37	1.08	0.46	0.00	0.46	0.00	0.46	0.27
Language[a]	3.13	2.23	2.01	0.97	1.54	2.01	1.98*	1.79	1.79	4.25	1.56	2.68	1.79	2.68	2.36*	− 0.67	0.45	0.89	0.67	0.89	0.44
Communication[b]	5.55	4.31	4.93	4.93	5.55	4.31	4.93*	5.55	4.93	3.70	4.93	5.55	5.55	4.93	5.02*	1.85	1.23	0.00	0.62	1.23	0.98
Socialization[b]	0.76	0.00	0.57	0.38	1.51	0.19	0.57	1.51	0.57	1.51	0.94	0.57	0.94	0.19	0.89	− 1.04	0.19	0.38	0.38	0.57	0.09

If the value of the reliable change index (RCI) is greater than 1.96, the difference in scores between the two intervals is statistically significant at a 95% confidence interval

JA Joint attention

*RCI mean of participants statistically significant

[a]Bayley-III

[b]Vineland-III

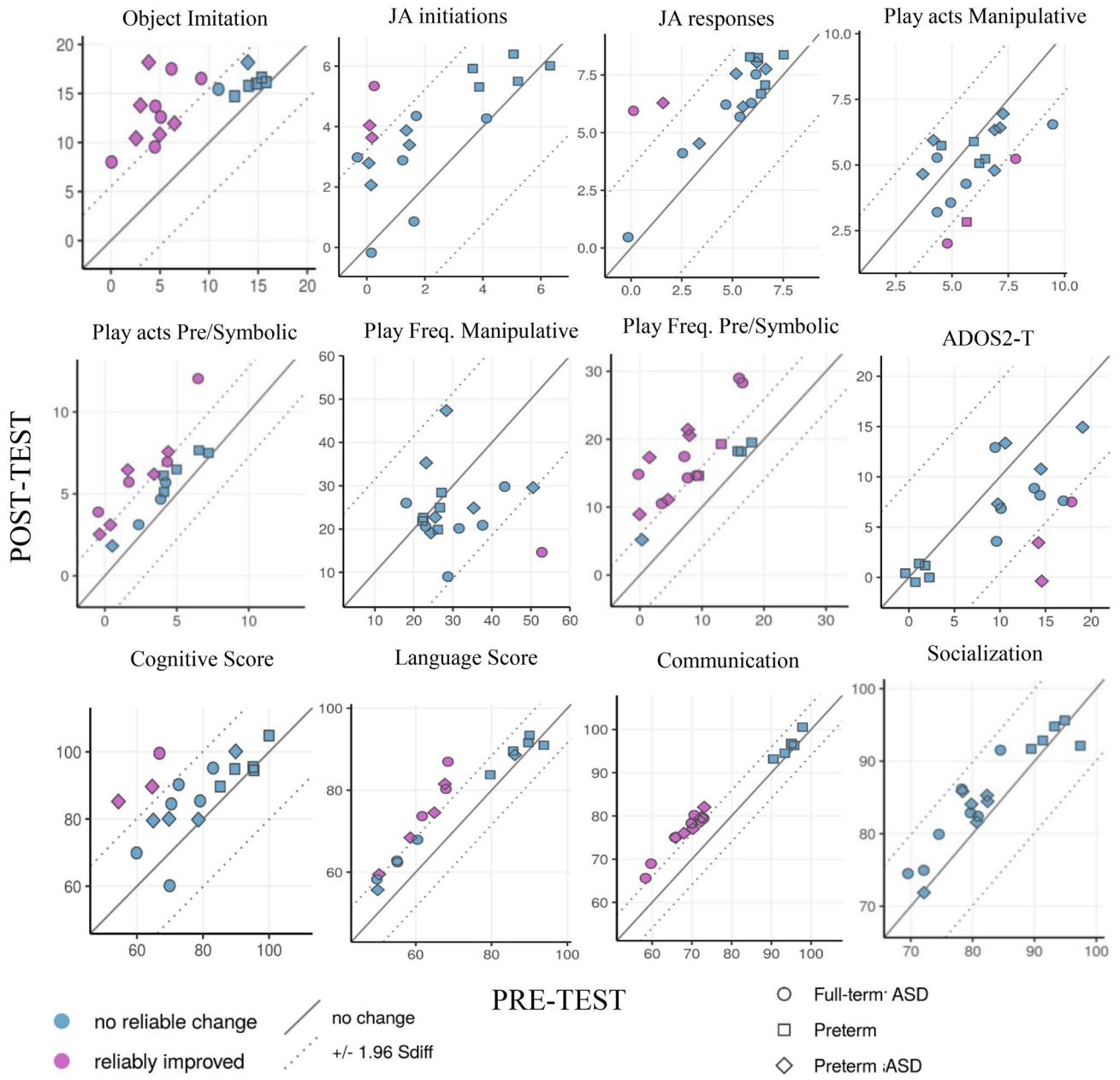

Fig. 3 Reliable Change Index by participant in each group. Participants out of the boundaries reliably improved

differences were found pre-treatment. This could be due to the fact that both groups display the same characteristics in terms of signs of ASD and its associated impairments. Even so, these results should be viewed cautiously, as this was a pilot study and there is little literature on the effect of early interventions on preterm and full-term children with ASD. When the three groups were compared, there were significant differences between the intervention groups and the control group in those instances where pre-treatment differences had been greater. Although the literature is limited, these results are comparable with other studies which compare difficulties in preterm children with ASD versus preterm children with no obvious ASD risk (Chen et al., 2020; Groote et al., 2006; Johnson et al., 2010). Future research should focus on intervention studies that compare preterm children with ASD with their non-risk peers and full-term children with ASD, in order to compare these with the results obtained by us and determine whether preterm children with ASD call for specific intervention procedures or actions.

Individual analyses showed that, with the exception of Joint Attention, the mean RCI for preterm children with ASD

was significant. These results could support group analysis of the effect size. The lack of reliable changes within the non-ASD preterm group suggests that this group's trajectory is stable over time. Although the RCI statistic is not commonly used in pre-post-treatment studies, it is nonetheless an extremely useful source of individual information. In cases where only pre- and post-treatment measures are available, a logical sequence of analytic steps would be (Estrada et al., 2019): (a) to assess individual changes via the RCI; and, (b) to perform a classical average-based effect size estimation, such as Cohen's *d*. This would not only help researchers ascertain whether an intervention has had a positive effect in each group, but would also enable decisions to be made about each particular case. Further research is needed to understand more about the respective intervention ingredients that would stimulate social development in preterm children with ASD who show limited social improvement.

Furthermore, the results of feasibility and acceptability study may provide valuable information useful in carrying out a full-scale trial early intervention with children with ASD. An economic evaluation should also be included to assess the cost effectiveness of the intervention. Parents of preterm children with ASD reported a barrier to assist to the program due to different medical appointments. To this, the intervention program was adapted to the agenda of each family. Services should consider families' schedules to increase the attendance ratios and reduce the attrition.

The results of this study are the first to show that preterm children with ASD acquire skills in areas considered to be core deficits of this disorder. The significance of these changes in specific skills is reinforced by some factors that were controlled for in the study. There is always the possibility that participants may engage in another intervention program during the course of a study. In our study, however, we controlled the intervention dosage. Although there was some variability in the number of treatment sessions which each child received, these differences were small and non-significant between groups. We also controlled how much and what type of treatment children received, by ensuring that all participants received 2 h per week of the same early intervention program. As reported by parents, no additional SCI programs were initiated while the children were under study.

Limitations and Future Research

Some limitations should be noted. First, the presence of pre-existing groups (preterm with ASD vs. full-term with ASD vs. preterm) meant that there were non-equivalent groups pre-treatment. However, these differences were offset by the Change Score analysis when it came to comparing groups. Using a repeated measures design, each subject was his/her own control when calculating gains, and the pre-test role acted as a covariate, thereby reducing the effect of pre-test differences. If groups are samples from two populations with different means, then regression of individual scores to the mean of their own population does not change the group means, and CS -rather than ANCOVA- may be unbiased (Van Breukelen, 2013). Hence, CS ANOVAs will outperform ANCOVAs in very small samples, and may produce far less biased effect estimates in a real-world situation (Kim, 2019). Randomized controlled trials (RCTs) are important in showing the effect of an intervention under ideal circumstances. However, it is important to show that, within a specific group (preterm children), a treatment is effective in a naturalistic setting where circumstances are not always ideal. RCTs also include a waitlist control group which provides stronger evidence. With a waitlist control group, the results can be compared directly with the experimental group. However, having a waitlist control group is not always the best option to start the program intervention as early as possible. Future research should study preterm children with ASD within the context of an RCT design.

Second, the present study is a pilot study, and it was based on a small sample size in each group. Despite the high prevalence of ASD in this group, approximately 143 preterm infants are born each year in the region where the study was conducted (data from Spain's National Institute of Statistics for the year 2018). With an ASD prevalence of 7% (Agrawal et al., 2018), there would be a maximum of 10 preterm infants with ASD per year. Due to the small sample of preterm children with ASD, it was not possible to have a control group with similar characteristics (with ASD). Though limited by the small sample size, findings from this study are nonetheless promising due to the positive outcomes found in early core characteristics of autism in preterm children with ASD. Robust statistics were therefore used, since these perform well for data drawn from a wide range of probability distributions, especially those that are not normal (Daszykowski et al., 2007). Also, there was not include a full-term control group in the study. However, the main goals were related to compare children attending the "ASD" and "Preterm" conditions. Data based a larger sample size and with a full-term control group will allow for a more in-depth analysis of factors affecting optimal treatment outcomes in this population.

Third, Children were recruited at 18 months old if they showed concern of ASD signs on the ADOS-2 and M-CHAT-R/F. After the intervention program, ASD diagnosis was confirmed at 24 months old. Although recent literature suggests that ASD diagnosis could become stable at this age, there is still controversy about the age at which a diagnosis of ASD is stable (from 24 to 36 months). Future studies should include a follow-up at 30–36 months to confirm the ASD diagnosis and support the results obtained in the field of ASD.

Finally, there were no follow-up data to assess the long-term impact of the treatment's effects. The limited follow-up allowed for only a brief examination of the intervention's sustainability. Future studies should therefore address these limitations in order to determine whether treatment effects vary at exit and follow-up. It is also critical to evaluate the efficacy of SCI against that of other treatments.

Conclusions

These results allow us to claim that change can be brought about in core developmental problems among preterm children with ASD, using a low-intensity intervention targeting social and communication skills. Even though such core areas of impairment are not easy to change, the intervention had an appreciable effect. Most of the participants improved significantly in socio-communicative skills, cognitive development, language, and adaptive behavior, and ASD signs were reduced. Our study adds to the literature which suggests that short-term focused interventions can reduce ASD impairments (Ingersoll, 2012). Accordingly, research into the longer-term effects of the intervention and a larger population of preterm children are needed, in order to examine possible mediators and moderators of intervention outcomes on children's social and communication abilities.

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Author Contributions ABM, RCB, and MMM designed the study; ABM and RCB wrote the manuscript; ABM, conducted the intervention program; ABM, MMM, AHF, SMD, PMG assessed families and children; ABM, MMM and EDV carried out statistical analyses and interpreted the results; MMM, AHF, EDV, CJR and MP collaborated in writing the manuscript. All authors have read and approved the final manuscript.

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Declarations

Conflict of interest All authors declare they have no conflicts of interest.

Ethical Approval Ethical approval was given by the Research Ethics Committee of the University of Salamanca, Spain (201700031949), and the Clinic Hospital of Salamanca, Spain (PI9910/2017).

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