Effectiveness of AI-Based Platform in Administering Therapies for Children with Autism Spectrum Disorder: A 12-Month Observation Study

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Abstract

Background: A 12-month longitudinal observational study was conducted on 43 children aged 2-18 years to evaluate the effectiveness of the Cognitivebotics AI-based platform in conjunction with continuous therapy, in improving therapeutic outcomes for subjects with Autism Spectrum Disorder (ASD).

Objective: The primary objective was to assess user engagement, assess the software's ability to log daily progress and evaluate efficacy using established clinical parameters across multiple domains.

Methods: Participants were divided into intervention and control groups and assessed using the Childhood Autism Rating Scale (CARS), Vineland Social Maturity Scale (VSMS), Developmental Screening Test (DST), and Receptive Expressive Emergent Language Test (REEL), at baseline (T1) and at the endpoint (T2).

Results: Subjects in the intervention group demonstrated statistically significant improvements across multiple scales, with reductions in CARS scores and gains in social, developmental metrics (social age, social quotient, developmental age, and developmental quotient), and language scores.

Conclusions: Overall, the platform was an effective supplement in enhancing therapeutic outcomes for children with ASD. This platform holds promise as a valuable tool for augmenting ASD therapies across cognitive, social, and developmental domains. Future development should prioritize expanding the product's accessibility across various languages, ensuring cultural sensitivity, and enhancing user-friendliness. Clinical Trial: CTRI/2023/06/054257

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Abstract and Keywords

Background:

A 12-month longitudinal observational study was conducted on 43 children aged 2-18 years to evaluate the effectiveness of the Cognitivebotics AI-based platform in conjunction with continuous therapy, in improving therapeutic outcomes for subjects with Autism Spectrum Disorder (ASD).

Objective:

This study evaluates the Cognitivebotic software's effectiveness in supporting children with ASD through structured, technology-assisted learning. The primary objectives include assessing user engagement, tracking progress, and measuring efficacy using standardized clinical assessments.

Methods:

A 12-month observational study was conducted on children diagnosed with ASD using the Cognitivebotics AI-based platform. Standardized assessments, include the Childhood Autism Rating

Scale (CARS), Vineland Social Maturity Scale (VSMS), Developmental Screening Test (DST), and Receptive Expressive Emergent Language Test (REEL), at baseline (T1) and at the endpoint (T2). All participants meeting the inclusion criteria were provided access to the platform and received standard therapy. Participants who consistently adhered to platform use as per the study protocol were classified as the intervention group, while those who did not maintain continuous platform use were designated as the control group. Additionally, caregivers received structured training, including online parent teaching sessions, reinforcement strategy training, and home-based activity guidance.

Results:

Subjects in the intervention group demonstrated statistically significant improvements across multiple scales. CARS scores reduced from 33.41 ± 1.89 at T1 to 28.34 ± 3.80 at T2 ($P < .00001$). Social Age (SA) increased from 22.80 ± 7.33 to 35.76 ± 9.09 (mean change: 12.96, 56.84% increase, $P < .00001$). Social Quotient increased from 53.26 ± 11.84 to 64.75 ± 16.12 (mean change: 11.49, 21.57% increase, $P < .00001$). Developmental Age (DA) showed an improvement from 30.93 ± 9.91 to 45.31 ± 11.20 (mean change: 14.38, 46.49% increase, $P < .00001$), while Developmental Quotient increased (DQ) from 70.94 ± 10.95 to 81.33 ± 16.85 (mean change: 10.39, 14.65% increase, $P < .00001$). REEL scores showed substantial improvements, with receptive language increasing by 56.22% ($P < .00001$) and expressive language by 59.93% ($P < 0.00001$).

In the control group, while most psychometric parameters showed some improvements, they were not statistically significant. CARS scores decreased by 10.62% ($P = .0625$), SA increased by 52.27% ($P = .0625$), SQ increased by 19.62% ($P = .125$), DA increased by 44.88% ($P = .0625$), and DQ increased by 11.23% ($P = .1875$). REEL receptive and expressive language increased by 34.69% ($P = .10035$) and 40.48% ($P = .05447$), respectively.

Conclusion:

Overall, the platform was an effective supplement in enhancing therapeutic outcomes for children with ASD. This platform holds promise as a valuable tool for augmenting ASD therapies across

cognitive, social, and developmental domains. Future development should prioritize expanding the product's accessibility across various languages, ensuring cultural sensitivity, and enhancing user-friendliness.

Keywords: Autism Spectrum Disorder, Neurodevelopmental disorders, Applied behaviour analysis, Software, Artificial intelligence

Main text:

Introduction

Autism, otherwise known as an autism spectrum disorder (ASD), is a neurodevelopmental disorder with a wide continuum of associated cognitive and neurobehavioral deficits, including, but not limited to, three core-defining features: impairments in social interaction, impairments in verbal and nonverbal communication, combined with restricted and repetitive patterns of behaviours [1]. Such impairments can impede an individual's social level of interaction, learning aptitude, and employability, leading to poor long-term outcomes, difficulties in socializing, poor job performance, and difficulties in activities of daily living [2-5]. The estimated prevalence of ASD has increased from 1 in 10,000 in the 1960s to at least 1 in 36 today [6-7].

The cause for the rise of children diagnosed with ASD is unknown [8]. What is clear is that early and consistent intervention is crucial to positive long-term outcomes [9]. Currently, there are no medical treatments that can effectively cure individuals with ASD, with most interventions involving applied behavioural analysis (ABA), speech and language therapy, and sensory integration to address the core symptoms of ASD [10, 11]. To provide adequate and quality therapy to children with autism, a team of trained professionals ranging from paediatricians, child psychiatrists, occupational, behavioural, and speech therapists, psychologists, specialist teachers, and dedicated caregivers are necessary[12]. Providing therapy to children with autism can be rewarding but challenging due to several factors. Figure 1 provides an insight into the challenges faced by the stakeholders in the care and support of children with autism.

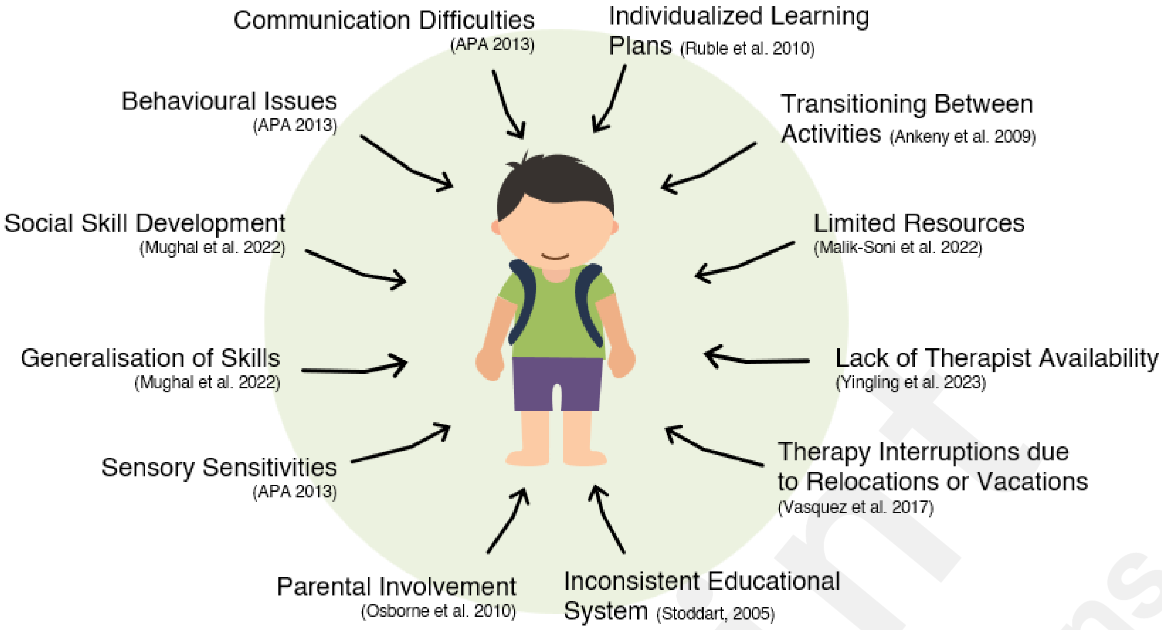


Fig. 1 Challenges in providing therapy to individuals with ASD.

As is, the solution to many of today's challenges; the leveraging of cutting-edge technologies to enhance autism intervention may be a viable option, ranging from the use of machine learning, deep learning in artificial intelligence (AI), animated gaming, and data analytics. Computer-assisted interventions (CAIs) are particularly appealing to under-resourced schools due to the potential to provide cost-effective individualized instruction and allow teachers to offer concurrent group instruction. Several available CAIs have integrated evidence-based interventions and complement current therapies for individuals with ASD [21].

Research suggests CAIs when applied effectively, can enhance learning by fostering four key components of the learning process: (I) active engagement, (II) group participation, (III) regular interaction and feedback, and (IV) integration with real-life settings [22]. Furthermore, the convenient access of CAIs among parents and therapists allows ease of access to these technologies right in the palm of their hands [23]. During the recent SARS-CoV-2 pandemic, there was significant disruption and reduction in conventional therapies. As a means to continue therapy, many therapists sought to use CAIs, leading to a jump of 15% to 61% usage [24].

Through the use of intelligent systems-based AI technologies, therapists and parents alike can provide supplementary and consistent therapy to individuals with ASD and enhance outcomes [25-

28]. In two recent articles, the prospect of integrating AI into standard practices for autism therapy has great potential to improve social and communication outcomes in individuals with autism [29-30].

The integration of video modelling in ABA allows the individual to observe a recorded video of a specific task, gradually enabling independent performance by clearly presenting the instructions and essential stimuli needed to complete the task. Several studies have demonstrated the effectiveness of this strategy across various complex social tasks, such as acquiring conversational skills, commenting, complimenting, and enhancing pragmatic abilities, as well as initiating and maintaining social relationships [31].

Gaming systems provides a sensory stimulus, where numerous studies have found an attraction factor for participation through a framework or application that provides additional animation and images [32-33]. AI-driven games can improve cognitive skills, social interaction, and emotional regulation. Such games can be modified to the specific needs of individuals with autism, offering personalized learning objectives. Studies have suggested that integrating AI-based interventions into standard therapy can improve the behavioural patterns of children with autism [34-35]. Animation games use engaging animated characters and scenarios to teach essential skills, making learning enjoyable and less stressful for children with autism. Thus, widening their attention span and having a greater retention of learned skills. Studies using animation-based interventions have observed significant improvements in language acquisition and social skills [36-37]. All these technology-driven solutions have been shown to significantly enhance outcomes and bridge the limitations of therapists and parents in managing challenging behaviours among children with ASD.

As a result, Cognitivebotics an AI-powered assistive technology was designed and developed. The platform allows both children with autism and the parents/therapists to effortlessly access its program anytime, anywhere since it only requires any gadget (laptop or tablet) and access to an internet connection. The development process involved a multidisciplinary approach, combining insights from clinical psychology, child development, and technology experts. The platform provides a "digital" VARK opportunity range (Visual, auditory, read/write, and kinaesthetic) to help children acquire social, communication, emotional, and behavioural skills, while automatically recording progress for therapists [38]. For parents, the platform is an easy-to-use digital tool offering training sessions on strategies and techniques, ensuring continuity of therapy at home. For further information on the platform, visit https://cognitivebotics.com/.

During the COVID-19 pandemic, a survey was conducted among therapists working with children diagnosed with ASD. Due to the reduction in conventional therapies, the therapists observed a moderate to severe impact on subjects' learning (73%), while parents were impacted emotionally and psychologically (85%). Before the pandemic, only 22% of therapists expressed a willingness to use any digital technology in autism intervention, however, this number tripled to 65% due to the constraints imposed by the lockdown [40]. There was an urgent need for standardising digital health technologies that can be parent-mediated [39]. An initial pilot study was conducted between November 2020 and April 2021 to assess the software's capabilities using a set of 19 different skills. Throughout the study, the software effectively collected and recorded data during the user interaction, demonstrating its effectiveness in real-time data collecting and analysis [40].

Subsequently, to further evaluate the effectiveness of the Cognitivebotics AI-based platform in augmenting therapies for individuals with ASD, an observational longitudinal study with an adequate sample size was conducted to assess different domains - the social/emotional, language/communication, and cognitive development of individuals who utilized the platform for 12 months. The initial study revealed minor glitches, which were promptly addressed, and parents of the individuals expressed a willingness to continue using the app, highlighting its potential impact.

Methods

The observational longitudinal study was designed to evaluate the effectiveness of the Cognitivebotics AI-based software over a 12-month period. By understanding the practical challenges and assessing the software's effectiveness, the study provides a foundation for future development and design of a trial.

The primary objectives of the study are as follows:

1. User Engagement: Assess the ability of both children and parents to effectively utilize the software and follow online instructions.

2. Progress Tracking: Evaluate the software's capability to automatically log the child's daily progress and provide visual graphical feedback on the dashboard.

3. Efficacy Measurement. Using established clinical parameters to evaluate progress at T1 and T2 across multiple measures:

Scoring Systems:

Qualified therapists conducted assessments at baseline and at a 1-year follow-up, using the following specific parameters to evaluate progress over time:

The **Childhood Autism Rating Scale (CARS)** score is a factor analysis–based scale used for assessing the presence and severity of symptoms of autism spectrum disorders [41]. The scores between 30-37 are grouped as mild to moderate Autism and scores between 38 to 60 are grouped as severe level of Autism. According to Russell et al. 2010, CARS has an acceptable level of sensitivity and specificity in Indian populations [42].

The **Vineland Social Maturity Scale (VSMS)** scores were compared between groups, assessing changes in social age and social quotient. This scale has been used to measure the adaptive behaviours of the children with or without ASD measuring the developmental profile in eight domains and scoring Social Age (SA) and Social Quotient (SQ). Originally developed by EA Doll in 1935, VSMS was adapted by A.J. Malin in 1956 to better suit the Indian population, ensuring its cultural relevance and applicability. This adaptation was further modified by Bharat Raj in 1992, incorporating additional changes [43-45].

The **Developmental Screening Test (DST)** scores, including developmental age (DA), and developmental quotient (DQ). Developmental Screening Test (DST) assesses the developmental progress of children across various domains, including motor skills, language, social behaviour, and cognitive abilities. It helps in determining the DA and DQ of the participants, which reflects their level of functioning in comparison to typical developmental milestones [46]. Recognizing that many developmental assessments at that time were standardized on Western populations, Bharatraj in 1977, adapted the DST to be more sensitive to the developmental norms of Indian children [47].

The **Receptive and Expressive Emergent Language Test (REEL**) scores are designed to identify infants and toddlers who have language impairments or who have other disabilities that affect language development. It has two core subtests, Receptive language age (RLA) and Expressive language age (ELA) that are based on caregiver reports and converted into age-equivalent scores. A study conducted on Hindi-speaking children, found REEL assessment to be valid, reliable, and effective in assessing language outcomes [48].

Recruitment

Recruitment for the study took place from January to April 2023 and the completion of the study was 12 months after the last subject was recruited. Parents whose children were diagnosed with ASD and attending Rainbow Hospital in India were identified by the clinical team. Recognizing individuals with ASD may have a higher chronological age but still have a lower social or developmental age, subjects were accepted by their social or developmental age is within 2 to 18 years. The Parent Information Sheet regarding the study was provided to all identified parents. Parents who expressed interest in their child's participation were contacted by the Principal Investigator's (PI) team. Table 1 shows the inclusion, exclusion, and withdrawal criteria of the study.

Table 1: Inclusion, exclusion, and withdrawal criteria for subjects

Inclusion Criteria	**Exclusion Criteria**
Subjects who met all the following inclusion criteria were enrolled in the study: 1. Children diagnosed with ASD using assessment scales such as CARS, etc. 2. Children between 2 to 18 years.	Subjects who met any of the following exclusion criteria were not eligible for participation in the study:

3. Children with associated comorbidities will be included on condition the child can use the platform. 4. Ability to understand and respond to instructions given in English. 5. Access to a device on which the software can be accessed using an internet connection. 6. Parents who have consented for their child to use the software.	1) Parents who are not willing to consent to the study. 2) No tablet, computer, or internet connection 3) Unable to understand English
Withdrawal Criteria/ Removal of Subjects from the Therapy or Assessment	
Any subject was allowed to voluntarily discontinue from the study at any time after giving informed consent and before the completion of the last visit of the study. This would not affect the care provided by their clinical team. The reasons for subject withdrawal were recorded and included, but are not limited to: 1. Subject is no longer willing to continue in the study. 2. Study termination by sponsor/IEC. 3. Investigator's discretion (for safety reasons). When a subject discontinued during the study period, the investigator clearly documented the reason in the medical records and completed the appropriate CRF page describing the reason for discontinuation. In addition, every effort was made to complete the appropriate assessment.	

Abbreviations: Autism Spectrum Disorder (ASD); Childhood Autism Rating Scale (CARS); Independent Ethics Committee (IEC), Case Report Form (CRF).

During this stage, the study objectives and procedures were thoroughly explained, and any questions from the parents were addressed. Informed consent was obtained from those who agreed to participate, and documentation was appropriately maintained. At baseline, clinical assessments including the CARS, DST, VSMS, and REELs were administered. Parent training sessions, conducted either online or offline, were arranged to familiarize parents with the platform and its usage. Parents who had training were granted access to the software and instructed to ensure their children used the software for at least 20 minutes per session, with a minimum of three sessions per day over 12 months, followed by Home-based activities to reinforce learning. At the beginning of the study, we requested parents to use software along with the standard care they were providing to their children and for ethical reasons didn't ask them to stop any other treatments or therapies.

Subjects were scheduled for three visits during the active study period:

- Visit 1 (Day 0, T1): Baseline clinical assessments were conducted.
- Visit 2 (6 months): Clinical parameters were reassessed.
- Visit 3 (12 months, T2): Final clinical assessments were conducted.

- Data from the software tracking the child's progress was collected for statistical analysis at each stage.

Additionally, a follow-up phone call was made every 15 days between the physical visits to verify the child's regular usage of the software and address any concerns. This telephonic follow-up ensured adherence to the study protocol and provided support for parents throughout the trial.

Software-delivered program

Using tablets or a computer, the platform offers evidence-based therapeutic interventions through a high-quality, patented software program, that addresses a broad spectrum of learning difficulties by learning small, key behaviours incrementally. This aims to improve learning outcomes and developmental progress in individuals with ASD by providing a comprehensive digital platform that supports various learning styles and therapeutic needs. It is designed to personalize learning, adjust difficulty levels, and provide real-time feedback and support to both parents and children.

Upon initially using the platform, parents are registered in the system and requested to complete an auto-generated Individualized Learning Plan (ILP) Questionnaire generated by the software. This enables the software to ascertain the child's current developmental state and learning needs. If there were any difficulties or queries from the parents on the questionnaire, a study coordinator was available to assist with the onboarding process. Parents will then be requested to attend a webinar session, where an interactive orientation on the software and its features will be given, and any queries will be addressed. Additionally, parents will receive a user manual and a navigation video for reference. Participation in this webinar session is mandatory before an ILP is assigned to the child.

Based on the parental responses and child assessments, an individualized learning plan (ILP) consisting of 3 target goals is generated by AI models focusing on 4 domains (social/emotional, language/communication, cognitive, and movement/ physical development). Table 2 contains the lesson plan within the software and its advantages in providing adjunct therapy to children with ASD. The content is personalized and mapped to individual learning objectives, guided by therapistdefined developmental goals.

Table 2: Lesson plan structure and associated advantages of the platform.

Goal/Skill Domain	Task / Learning Objective	Methodology & Advantages
Eye Contact / Attention	Looking at the object	Gamified, visually engaging content designed for children with neurodiverse profiles. Encourages sustained visual attention through interactive elements.
Eye Contact / Attention	Responding to name	Multimodal cues and visual prompts enhance auditory responsiveness and social awareness.
Imitation Skills	Imitating arm, leg, or facial movements	Structured video models guide imitation in a low-anxiety, judgment-free digital space.
Cognitive Skills	Number identification, shape recognition	Tasks scaffold foundational academic concepts in a playful, exploratory manner.
Communication / Language	Labeling objects, requesting help	Activities promote expressive and receptive communication. Co-viewing with caregivers enhances language modeling.

Before engaging in any lessons, parents are encouraged to watch the objective videos to improve the reasoning of mastering each goal. A practice session is available for skill reinforcement; however, the scores in these practice sessions are not recorded for progression to the next stage. Daily, each practice session will last 20 minutes. The software automatically concludes the learning session and redirects the child to the dashboard. If the caregiver determines that the child is prepared for an additional session, they have the option to initiate a new session., Overall, there are 227 activities or tasks organized under goals. Figure 2 presents the technologies and features of the Cognitivebotics platform.

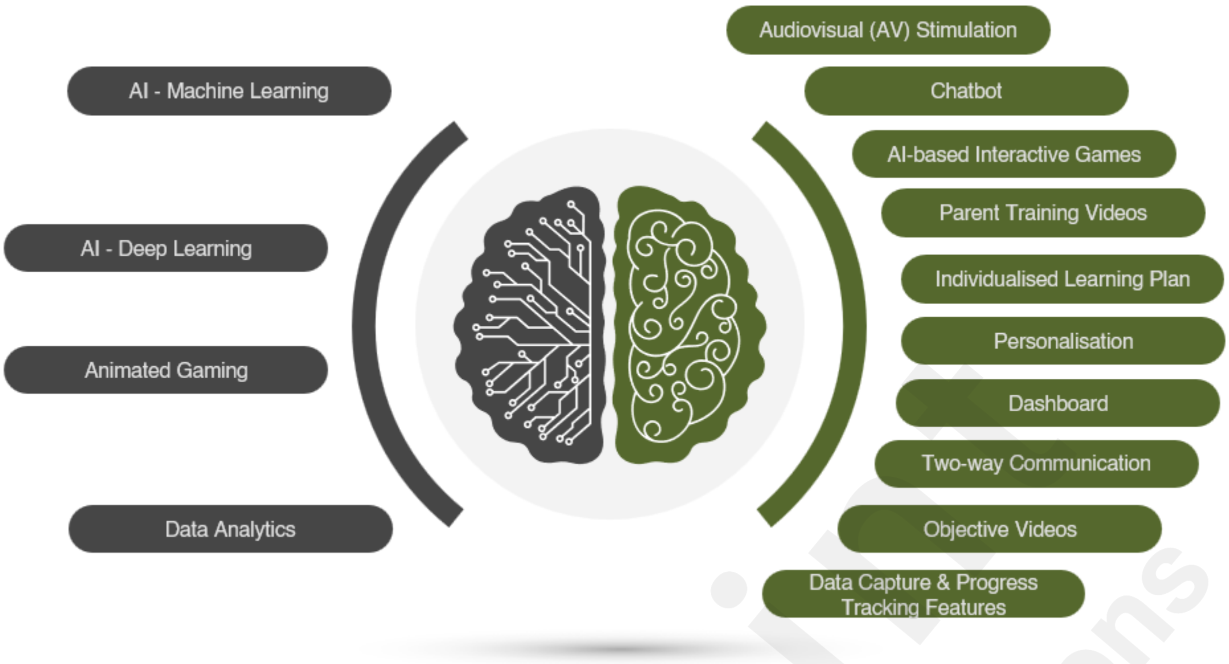


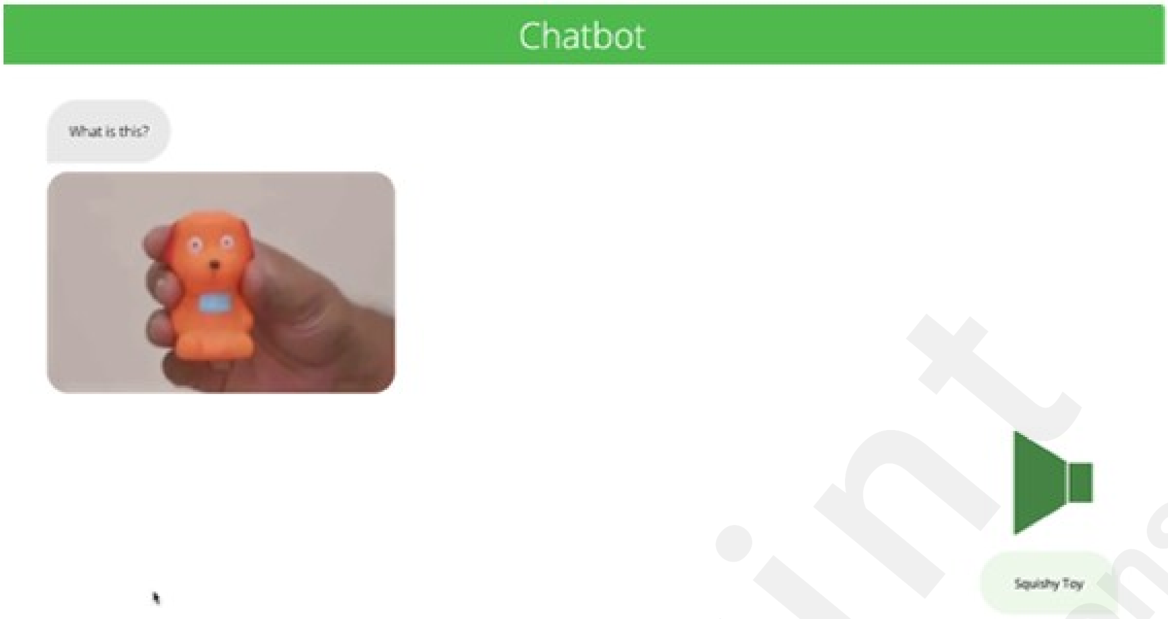
Fig. 2 The technologies and features in the software.

The session begins with the caregiver launching the daily schedule on the Cognitivebotics app. This schedule presents a sequence of personalized tasks aligned with the child's developmental goals. Each task is supported by engaging, gamified digital content designed specifically for children with ASD. Caregivers are encouraged to co-view and participate in the learning process, fostering emotional bonding and reinforcing engagement through shared experience. Alternatively, under parent supervision, the child may explore the content independently, depending on their comfort and developmental level.

Once the child achieves 3 goals, a new individualized learning plan ILP with a new set of 3 goals will be created. To achieve each goal, the child is taught through 4 modalities:

Audiovisual (AV) Stimulation: Concepts are introduced through video modelling with interactive questions embedded within the content, increasing with complexity across four levels (Level 0, 1, 2, 3). Prompts are provided to guide the child's learning and are gradually reduced as the child becomes more proficient.

Chatbot (CB): This feature utilizes interactive questions to reinforce learning and promote generalization. The feature is particularly effective in fostering verbal engagement and enhancing the child's communication skills. An example of chatbot goal is given in fig3.



Software: *"Hi [Child's Name]! Let's name the object"*
([*Object*] *appears on the screen...*)
Software: *[Child's name]!* What is this?
(Child should respond "Squishy toy"
(*If the child does not respond, the caregiver points at [object] on the screen*)
Software: *What is this?*
(*If the child still does not respond...*)
Software: *"Squishy Toy". [Child's Name] say "Squishy toy."*
(*If the child responds...*)
Software: *"Great job, [Child's Name]! Let's continue!"*
(*If the child did not respond...*)
Software: *"Great job, [Child's Name]!*
(Software moves on to the next goal and repeats this lesson the next day until the child masters the goal.

Fig 3.A screenshot of a lesson and the transcript of child-software interaction. **AI-Based Interactive Games:** Learning is facilitated through AI-driven interactive games that are tailored to each child's learning style, making the learning engaging and adaptive to individual needs.

Home-Based Parents Training Videos: To support home-based activities, parents are provided with instructional videos that demonstrate how to apply the skills learned by their child in various settings, thus reinforcing learning outside the therapy centre.The child's performance is assessed using three metrics captured by the software: First-Time Rights (accuracy of initial responses), Correct

Questions (total number of correctly answered questions), and Number of Questions Attempted (total engagement with the learning material). Once the lesson is mastered, the software automatically assigns the next set of goals.

If a child is not progressing towards their goals, the system proactively alerts the parents and therapists. Separately, parents are instructed to record a video of the lesson and submit it to the study coordinator or therapist team for review. In response, therapists will simplify the online goals to better suit the child's needs. Should the child continue to struggle, parents will receive a notification prompting them to resubmit the ILP checklist. Following this, the system will reassign three new goals, which will be carefully verified by therapists to ensure they align with the child's learning trajectory.

Other core features of the platform

Individualized Learning Plan (ILP) Progression: The software adjusts the level of difficulty of the ILP based on the child’s progress, providing necessary assistance and notifications to parents and therapists.

Personalization: Personalization is a unique feature, where all learning goals are delivered in a personalized and customized manner, tailored to the specific needs of each child. During interactive sessions, the system personalizes by using the child’s name while shooting the interactive questions drawing the child’s attention.

Dashboard: A daily progress graph is displayed on the child’s dashboard, which is accessible to both parents and therapists, offering real-time insights into the child's development.

Two-way communication: The software includes a fun activity that detects and encourages body part interactions, in addition to occupational therapy tasks, promoting overall development from a young age.

Objective Videos: Parents are empowered through videos that outline the objectives of each task, enabling them to actively participate and support their child's learning.

Data Capture and Progress Tracking features: Aims to automate monitoring and capture the child's progress based on key learning principles—attention, retention, and generalization, such as 'Eye Gaze Detection'. This data is presented in a user-friendly format on a dashboard, facilitating easy comprehension for both parents and therapists.

Fidelity of Implementation Data

The fidelity of implementation was assessed via a multi-tiered approach to ensure attendance to the session lessons. The software has an automated session notification and progress tracker to prompt parents to complete assigned goals within the learning plan. To progress to the next learning level, mandatory successive mastering of goals is required. This ensures that all lesson components were completed as intended. Additionally, therapist-led monitoring and follow-up calls were conducted to monitor progress, reinforce engagement with the intervention, and address any caregiver-reported concerns to ensure fidelity.

Caregivers underwent a structured training program on reinforcement strategies aimed at ensuring consistency in their interactions with the child beyond software-guided sessions. This training equiped caregivers with evidence-based behavioral techniques that align with the principles of Applied Behavior Analysis (ABA) and developmental learning models. such as Immediate Reinforcement or reward systems. Furthermore, to encourage parental involvement, caregivers were provided zero-fee in-person therapy sessions at the center, on the condition their child is actively engages with the platform.

Lastly, software usage was collected at the backend, tracking metrics such as log-in frequency, time spent on lessons, and completion rates. This allowed the software programmer to evaluate the platform utilization and adherence. Any deviations from the lesson plans were brought to the attention of the therapist. Together, these mechanisms ensured consistent implementation and provided opportunities for timely intervention when necessary.

Statistical analysis

After completion of the study, the data were analysed to compare the effectiveness of the Cognitivebotics platform between the intervention and control groups. For each group and clinical assessment parameter, the mean scores and standard deviations were calculated at two stages: the start of the study (T1) and the end of the study (T2). The mean change and percentage mean change from T1 to T2 were also computed. To determine the statistical differences, the *P*-values were calculated using the Mann-Whitney U test, with a *P*-value of $<.05$ being considered as statistically significant.

Results

The results of this study examine the impact and utility of the Cognitivebotics platform for children with ASD over a 12-month observational period. Key outcomes focus on quantitative measures of behavioural, developmental, and language-based parameters. An intervention versus control analysis was performed, organized by baseline (T1) and end-of-study (T2), to ascertain the software’s impact across multiple functional and developmental domains, namely CARS, VSMS, DST, and REEL scores. This approach provided structured insights into the software's influence on each parameter and allowed for comparative analysis of outcomes over time.

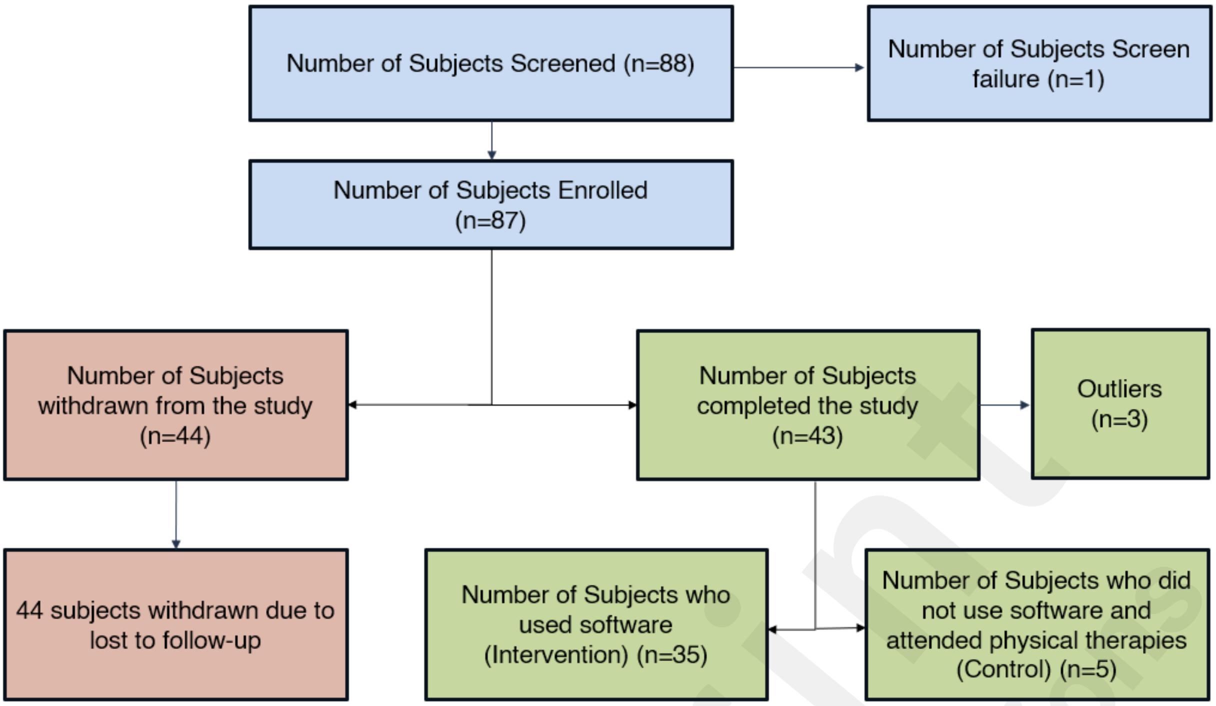


Fig. 4 Flowchart of subjects in the study.

Figure 3 illustrates the study's recruitment and retention flow. Out of an initial total of 88 enrolled subjects, 43 subjects completed the study, whereby 35 subjects continued to use the software for the entire 1-year duration, and 5 subjects did not use the software but participated in the 1-year follow-up assessments, and were categorised as the control group. A further 3 subjects were labelled as outliers and excluded from further analysis. Table 2 shows the key baseline demographic characteristics of the 40 subjects who completed the study.

Table 3: Comparison of baseline demographics in subjects in Intervention and control groups.

Parameter	Statistics	Intervention	Control	Overall
Age	n	35	5	40
	Mean ± SD	43.71 ± 15.48	44.60 ± 14.98	43.83 ± 15.23
	Median	39.00	39.00	39.00
	Quantile	31.50;52.00	33.00;54.00	31.75;54.50
	Range	25.00 - 87.00	31.00 - 66.00	25.00 - 87.00
Gender	n	35	5	40
	Male	33 (94.29%)	3 (60.00%)	36 (90.00%)
	Female	2 (5.71%)	2 (40.00%)	4 (10.00%)

Abbreviations: Total number of subjects (n); Standard Deviation (SD).

The subjects in intervention group were stratified into three developmental groups based on chronological age:

- Toddler Group (n = 12): Children aged 2–3 years
- Preschool Group (n = 15): Children aged 4–6 years

- School-Aged Group (n = 8): Children aged 7–8 years

The purpose was to assess the impact of the intervention across different developmental ages, considering variations in cognitive, language, and social skills.
Based on the study location, the majority of participants were of South Indian descent and from families with a higher education background. All participants showed delays across multiple developmental domains, necessitating structured therapeutic intervention. Their academic skill levels in reading, writing, and mathematics were rudimentary, with significant challenges observed in social/emotional, language/communication, cognitive, and movement/physical development.

Intervention and Control group-based analysis using different parameters

The study evaluated outcome measures in intervention and control groups across T1 (baseline) and T2 (12 months), assessing CARS, SA, SQ, DA, DQ, and REEL scores.

Table 4 shows the outcome measures of 35 subjects in the intervention group, which were compared across T1 and T2:

In the CARS score, there was a significant decrease from 33.41 ± 1.89 at T1 and 28.34 ± 3.80 at T2 showing a mean change of 5.07 and a percentage change of 15.18 % (P = .00001).

In the SA score, there was a significant improvement from 22.80 ± 7.33 at T1 and 35.76 ± 9.09 at T2 with a mean change of 12.96 and a percentage change of 56.84 % (P = .00001).

In the SQ score, there was an improvement from 53.26 ± 11.84 at T1 and 64.75 ± 16.12 at T2 with a mean change of 11.49 and a percentage change of 21.57 % (P = .00001).

In the DA score, there was an improvement from 30.93 ± 9.91 at T1 and 45.31 ± 11.20 at T2 showing a mean change of 14.38 and a percentage change of 46.49% (P = .00001).

In the DQ score, there was an improvement from 70.94 ± 10.95 at T1 and 81.33 ± 16.85 at T2 showing a mean change of 10.39 and a percentage change of 14.65% (P = .00001).

In the REEL score, the RLA showed a substantial increase from 22.09 ± 8.94 at T1 to 34.51 ± 14.93 at T2, with a mean change of 12.42 and a percentage change of 56.22 % (P = .00001). Similarly, the ELA exhibited a significant increase from 18.69 ± 8.52 to 29.89 ± 15.60 showing a mean change of 11.20 and a percentage change of 59.93 % (P = .00001).

Table 4: Comparison of outcome measures in the intervention group only at baseline (T1) and end of

study (T2).

Parameters	Intervention Group (n = 35)				
	T1	T2	Mean change	Percentage Mean change	P P-value
CARS	33.41 ± 1.89	28.34 ± 3.80	5.07	**15.18 %**	**<.00001**
SA	22.80 ± 7.33	35.76 ± 9.09	12.96	**56.84 %**	**<.00001**
SQ	53.26 ± 11.84	64.75 ± 16.12	11.49	**21.57 %**	**<.00001**
DA	30.93 ± 9.91	45.31 ± 11.20	14.38	**46.49%**	**<.00001**
DQ	70.94 ± 10.95	81.33 ± 16.85	10.39	**14.65%**	**<.00001**
RLA	22.09 ± 8.94	34.51 ± 14.93	12.42	**56.22 %**	**<.00001**
ELA	18.69 ± 8.52	29.89 ± 15.60	11.20	**59.93 %**	**<.00001**

**Note: T1- Start of the study; T2-End of the Study; p-value is calculated using Mann-Whitney U test. Abbreviations: Childhood Autism Rating Scale (CARS); Social Age (SA); Social Quotient (SQ); Developmental Age (DA); Developmental Quotient (DQ); Receptive language age (RLA); Expressive language age (ELA).*

Table 5 shows the outcome measures of 5 subjects in the control group, which were compared across T1 and T2:

In the CARS score, there was a significant decrease from 33.90 ± 1.24 at T1 and 30.30 ± 3.68 at T2 showing a mean change of 3.6 and a percentage change of 10.62 % (*P* = .0625).

In the SA score, there was a significant improvement from 21.41 ± 5.44 at T1 and 32.60 ± 8.24 at T2 with a mean change of 11.19 and a percentage change of 52.27 % (*P* = .0625).

In the SQ score, there was an improvement from 49.13 ± 5.45 at T1 and 58.77 ± 14.73 at T2 with a mean change of 9.64 and a percentage change of 19.62 % (*P* = .125).

Similarly, in the DA score, there was an improvement from 28.30 ± 6.69 at T1 and 41.00 ± 7.04 at T2 showing a mean change of 12.7 and a percentage change of 44.88 % (*P* = .0625).

In the DQ score, there was an improvement from 65.60 ± 11.68 at T1 and 72.97 ± 7.22 at T2 showing a mean change of 7.37 and a percentage change of 11.23 % (*P* = .1875).

In the REEL score, the RLA showed a substantial increase from 19.60 ± 7.13 at T1 to 26.40 ± 9.53 at T2, with a mean change of 6.80 and a percentage change of 34.69 % (*P* = .10035). The ELA exhibited a significant increase from 16.80 ± 4.60 to 23.60 ± 6.23 showing a mean change of 6.80 and a percentage change of 40.48 % (*P* = .05447).

Table 5: Comparison of outcome measures in the control group only at baseline (T1) and end of study (T2).

Parameters	**Control Group** (n = 5)				
	T1	**T2**	**Mean change**	**Percentage Mean change**	***P*-value**
CARS	33.90 ± 1.24	30.30 ± 3.68	3.6	**10.62 %**	.0625
SA	21.41 ± 5.44	32.60 ± 8.24	11.19	**52.27 %**	**.0625**
SQ	49.13 ± 5.45	58.77 ± 14.73	9.64	**19.62 %**	**.125**
DA	28.30 ± 6.69	41.00 ± 7.04	12.7	**44.88 %**	**.0625**
DQ	65.60 ± 11.68	72.97 ± 7.22	7.37	**11.23 %**	**.1875**
RLA	19.60 ± 7.13	26.40 ± 9.53	6.80	**34.69 %**	**.10035**
ELA	16.80 ± 4.60	23.60 ± 6.23	6.80	**40.48 %**	**.05447**

**Note: T1- Start of the study; T2-End of the Study; P-value is calculated using Mann-Whitney U test. Abbreviations: Childhood Autism Rating Scale (CARS); Social Age (SA); Social Quotient (SQ); Developmental Age (DA); Developmental Quotient (DQ); Receptive language age (RLA); Expressive language age (ELA).*

Overall, the intervention group presented substantial improvements across all outcome measures, particularly in CARS, SA, and language scores (RLA and ELA), with the majority of these changes reaching statistical significance. This indicates that the platform may enhance social, cognitive, and language outcomes in the intervention group. In contrast, the control group of 5 subjects showed positive changes but with less significance and was statistically weaker across measures.

Discussion

The current study has demonstrated that Cognitivebotics, an AI-powered assistive technology has made significant gains in the developmental and social parameters over the course of 12 months in children diagnosed with autism. Both parents and therapist have reported minimal negative behavioural changes while using the platform, including screen addiction and sleep disturbances. In intervention versus control analysis, there were significant improvements in the intervention group, particularly in those with higher baseline levels of functioning, underlining the efficacy of the software in reducing autism severity and enhancing developmental skills in subjects with ASD. Accompanied by highly significant *P*-values, the intervention group showed improvement in symptoms, and marked enhancements in social skills, developmental age, and language abilities.

The Cognitivebotics software like many other available ABA-assistive technologies is observed to have various benefits and advantages specifically for individuals with ASD [49]. Supported in laptops, and tablets, the platform is commonly available, affordable, and socially acceptable, making it an ideal tool for parent-mediated interventions [50, 51]. Using the platform, parents played a crucial role in supporting their children’s learning, observing better improvements compared to the control group following traditional therapy. The software helps enhance attention span and motivation during learning activities, offering engaging, interactive experiences that increase children’s participation [52, 53].

Within a learning environment, the software increases interaction and participation and improves the learning process [54]. Additionally, the software provides real-time feedback on key skills and is customizable to focus on individual needs, similar to the benefits seen in the Picture Exchange Communication System (PECS) and other visual aids, text, and sounds [55, 56]. The portability of the devices can allow parents to provide learning at times when the child is most receptive, despite the unavailability of therapists. Furthermore, parent-implemented technologies can be the most readily and affordably deployed, and such assistive technology enables parents to offer the most opportunities for social contact [57]. The software incorporates interactive games that improve social-emotional functioning and behavior. The interactive feature allowed the subjects to recognize emotions, use deconfliction strategies, collaborate with others, and address issues like greeting known people like teachers or neighbours. In a recent study, parents who used social skills programs incorporating features similar to those in the Cognitivebotics platform found significant improvements in social skills and reductions in problematic behaviours, in contrast to those in the control group [58].

There may be certain shortfalls with the use of ABA assistive technologies, but as with any problem, there are solutions that can overcome such shortfalls. The first area of concern is increased screen time, possibly leading to restricted or repetitive behaviours, lack of socializing, and concerns over metabolic and sleep disturbances [59,60]. In such circumstances, Cognitivebotics has incorporated a pre-set screen time feature of 20 minutes, after which the session concludes and takes the user to the dashboard. It is also advisable to provide minimal access in a group setting to reduce potential isolation [61]. Devices may also be misused to view passive content, in which case supervised co-viewing with parents is advised [62]. Furthermore, the choice of content has to be predetermined, whereby highly interactive and engaging media is most beneficial to the child as it promotes engagement, motivation, and learning outcomes [63]. Another issue is the potential for tantrums if the device is removed. As is the case, when access to preferred items is interrupted, parents and therapists should be trained to control such behaviours.

In recent years, there have been numerous studies on the proposed use of tablets, or computers in autism intervention. A meta-analysis conducted by Sandbank et al. 2023, reviewed 252 separate trials examining the efficacy of technology in autism interventions [65]. The findings suggest an overall improvement in social communication skills and reductions in difficult behaviours, particularly when used by parents. This aligns with the intentions behind the Cognitivebotics platform, which aims to support individuals with autism and their families. Furthermore, a low incidence of adverse events reported in using such interventions supports the software adoption for both home and clinical settings.

Novack et al. 2019 conducted a study to assess the effectiveness of mobile applications on the principles of Applied Behaviour Analysis (ABA), particularly in assessing the impact on the receptive language skills of subjects. Randomised into immediate-treatment or a delayed-treatment control group, the results show significant improvements in receptive language skills in the former group [65]. However, the study had limitations, particularly with the absence of psychometric parameters to assess outcomes. While improvements in receptive language skills were observed, the study is incomplete. Our 12-month study demonstrated how Cognitivebotics leverages AI to improve receptive language skills, offering prolonged benefits using personalized ABA-based interventions and addressing limitations in traditional psychometric assessments. Another study aiming at addressing social engagement by using a proposed 3D Complex Facial Expression Recognition (3CFER) system to recognize facial emotions, found users in 3 weeks had marked improvement in identifying facial cues compared with control, with surprise and shy expressions being the easiest to identify [66]. Similarly, Cognitivebotics contains activities that enable children to better recognize and respond to social and emotional cues, significantly boosting their social communication skills within a short intervention period.

A study conducted in Saudi Arabia assessed the effectiveness of AI-driven apps in a traditional education setup. The inclusion of apps such as "My School" and "Alfaz," were chosen for their adaptive and interactive content that aligned with the academic curriculum. Participants who received 60-minute sessions twice weekly for five weeks showed significant improvements in reading and math skills compared to those in the control group. [67]. Similarly, our software incorporates real-time feedback, task adaptation, and data-driven insights to ensure that children receive targeted, engaging, and effective support, ultimately enhancing their cognitive and functional independence.

Lastly, a meta-analysis conducted by Moon et al. aimed to review the effectiveness of mobile device applications in the treatment of individuals with ASD. After a review of 1100 randomized controlled trials (RCTs), only 7 studies were deemed suitable for further analysis, suggesting a high methodological approach. Using the Mullen Scales of Early Learning, the results favoured the intervention group, indicating a significant improvement in the participants' early learning and developmental outcomes compared to control groups. Moreover, the analysis found minimal heterogeneity ($p>0.1$) across different studies or no significant evidence of publication bias. Correspondingly, our platform aligns with these findings by offering a technology-based, interactive tool specifically designed to enhance learning and developmental progress in individuals with autism. With an emphasis on providing individualized interventions that target key skills, Cognitivebotics uses validated clinical parameters to monitor improvements, reducing inaccuracies, similar to the studies highlighted in Moon's analysis [23].

Limitations of the study:

Although evidence from our longitudinal study shows significant improvement in outcome measures for individuals with ASD using the software, a few limitations have to be discussed. Firstly, the small sample size of 40 subjects is a critical limitation, suggesting inadequate generalisation of the findings. However, most studies regarding children with autism, often face challenges in recruiting adequate numbers of participants. Limited research has explored effective strategies for efficiently recruiting participants with ASD, posing a barrier to larger and more comprehensive studies in this field [68].

Secondly, the participants were recruited from a single centre and predominantly came from literate and urban families. Such a demographic is not representative of the entire population of individuals with ASD, particularly in India. The benefits observed in using the software may not translate to individuals with a lower socioeconomic status or located in rural areas, who may face different challenges and have different needs. Further studies should be conducted to include participants from rural areas and various socio-economic backgrounds. This includes incorporating features that reflect local languages and cultural sensitivities to ensure the software is relevant and effective for a wider range of users.

Thirdly, the study experienced a 59% attrition rate, which could be attributed to several factors, including language barriers or the demanding schedules of caregivers, which may have limited their ability to fully engage with the platform. Such high levels of attrition are commonly observed in digital therapeutics for mental health. Similarly, a recent meta-analysis found more than half of the users discontinued using smartphone apps aimed at treating depressive symptoms [69].

Finally, while randomized controlled trials (RCTs) are considered the gold standard for assessing the effectiveness of the intervention, their feasibility in such a population remains challenging. To address this, future research should explore methodologies that balance scientific rigor with practical implementation to further validate the software's effectiveness among different subgroup.

Conclusion

The 12-month study demonstrates that the Cognitivebotics platform delivering parent-mediated interventions has significantly improved multiple developmental and social parameters in participants. Furthermore, it highlights that these digital technologies using audio-visual, AI-based interactive games, animation games, and chatbots have an attraction factor that keeps the interest of these children with ASD. Particularly, the incorporation of AI into digital technology has been shown to enhance social communication skills, especially in younger subjects with learning difficulties to reach their specific learning objectives.

Most assistive technologies are not intended to satisfy the necessities of individuals suffering from ASD entirely, as they have variable needs. Despite being in its infancy, these digital technologies have been proposed to address the wide array of learning needs and work on the core symptoms of ASD. Further research must be conducted to include a larger number of children with different levels of social and developmental delays and ASD severity along with regional, linguistic, and socio-cultural variations.

In conclusion, the promising results of this study underscore the potential of AI software interventions in revolutionizing the holistic support for children with ASD. As these technologies continue to evolve, aligning the software not just to the needs of the child but to parents' and therapists' needs, offers a hope for more personalized and effective strategies for not just children on the autism spectrum but also neurodiverse children.

Ethical Considerations

This study was conducted in accordance with the study protocol, the New Drugs and Clinical Trials Rules 2019 issued by the Government of India, the ethical principles that have their origin in the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013), the International Council for Harmonisation (ICH) Good Clinical Practice (GCP), and all applicable local regulatory requirements. The investigators agreed to conduct the study according to the principles of the ICH GCP, and in accordance with the ethical principles that have their origin in the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013), the protocol, and all national, state, and local laws or regulations. The medical care given to, and a medical decision made on behalf of study subjects was always the responsibility of a Principal (Site) Investigator (PI). Each individual involved in conducting the study was qualified by education, training, and experience to perform his or her respective task(s).

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Consent to participate

Informed consent was obtained from the parents or legal guardians of all participants. The study details were thoroughly explained, including its purpose, procedures, and the voluntary nature of participation. Parents were informed that they and their children were free to withdraw from the study at any time, with no impact on their routine activities or any other services received.

Conflicts of interest

The primary author is on the Advisory Board of CognitiveBotics. The primary author was also actively involved in designing the study methodology and contributed to drafting and revising the manuscript.

The Principal Investigator (PI) conducted research at the study site and received an honorarium for overseeing the study's execution. The corresponding author is currently employed at Cognitivebotics Technologies Private Limited.

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Inclusion Criteria	**Exclusion Criteria**
Subjects who met all the following inclusion criteria were enrolled in the study: 7. Children diagnosed with ASD using assessment scales such as CARS, etc. 8. Children between 2 to 18 years. 9. Children with associated comorbidities will be included on condition the child can use the platform. 10. Ability to understand and respond to instructions given in English. 11. Access to a device on which the software can be accessed using an internet connection. 12. Parents who have consented for their child to use the software.	Subjects who met any of the following exclusion criteria were not eligible for participation in the study: 4) Parents who are not willing to consent to the study. 5) No tablet, computer, or internet connection 6) Unable to understand English
Withdrawal Criteria/ Removal of Subjects from the Therapy or Assessment	
Any subject was allowed to voluntarily discontinue from the study at any time after giving informed consent and before the completion of the last visit of the study. This would not affect the care provided by their clinical team. The reasons for subject withdrawal were recorded and included, but are not limited to: 4. Subject is no longer willing to continue in the study. 5. Study termination by sponsor/IEC. 6. Investigator's discretion (for safety reasons).	

When a subject discontinued during the study period, the investigator clearly documented the reason in the medical records and completed the appropriate CRF page describing the reason for discontinuation. In addition, every effort was made to complete the appropriate assessment.

Parameter	**Statistics**	**Intervention**	**Control**	**Overall**
Age	n	35	5	40
	Mean ± SD	43.71 ± 15.48	44.60 ± 14.98	43.83 ± 15.23
	Median	39.00	39.00	39.00
	Quantile	31.50;52.00	33.00;54.00	31.75;54.50
	Range	25.00 - 87.00	31.00 - 66.00	25.00 - 87.00
Gender	n	35	5	40
	Male	33 (94.29%)	3 (60.00%)	36 (90.00%)
	Female	2 (5.71%)	2 (40.00%)	4 (10.00%)

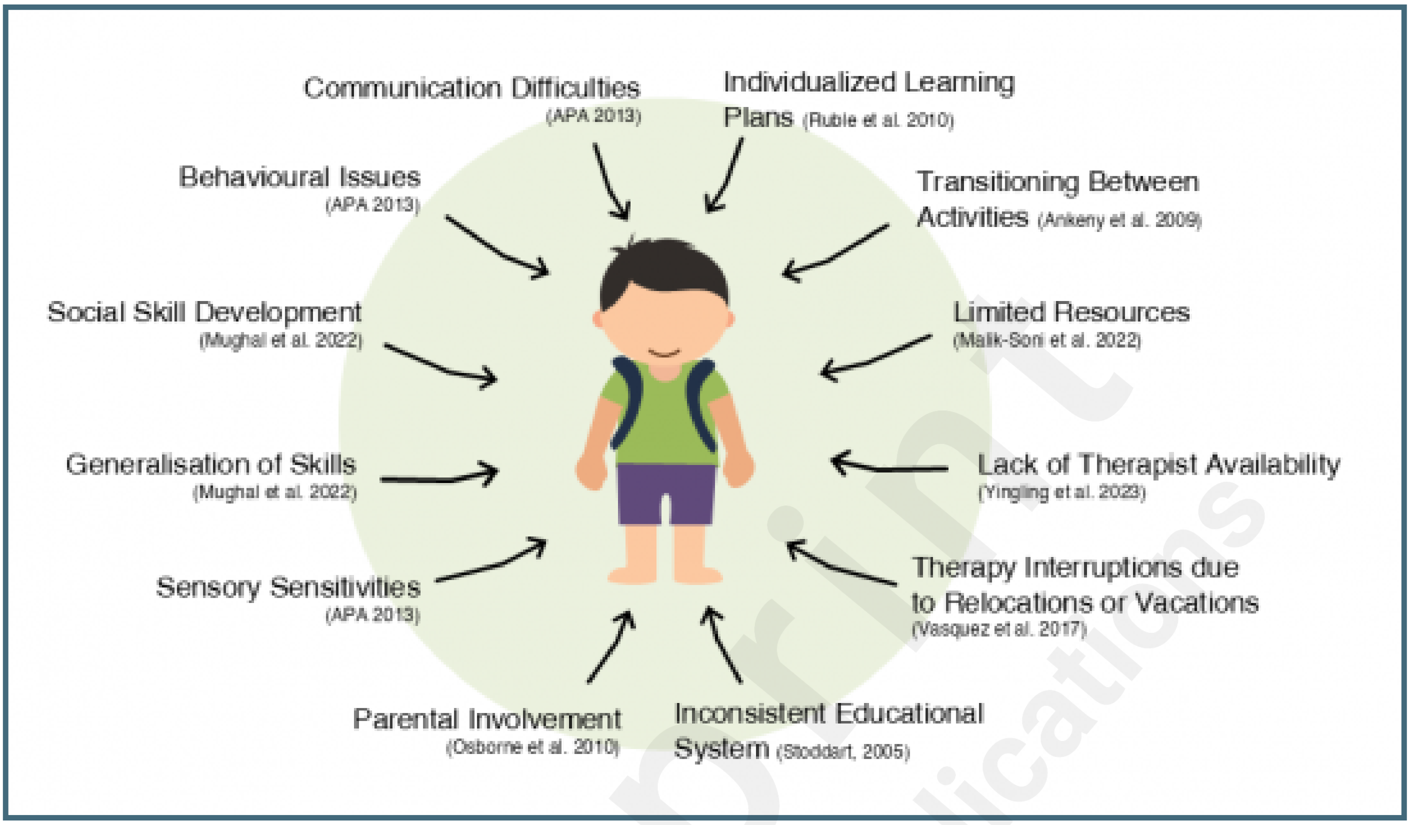
Parameters	**Intervention Group** (n = 35)				
	T1	**T2**	**Mean change**	**Percentage Mean change**	***P* -value**
CARS	33.41 ± 1.89	28.34 ± 3.80	5.07	**15.18 %**	**<.00001**
SA	22.80 ± 7.33	35.76 ± 9.09	12.96	**56.84 %**	**<.00001**
SQ	53.26 ± 11.84	64.75 ± 16.12	11.49	**21.57 %**	**<.00001**
DA	30.93 ± 9.91	45.31 ± 11.20	14.38	**46.49%**	**<.00001**
DQ	70.94 ± 10.95	81.33 ± 16.85	10.39	**14.65%**	**<.00001**
RLA	22.09 ± 8.94	34.51 ± 14.93	12.42	**56.22 %**	**<.00001**
ELA	18.69 ± 8.52	29.89 ± 15.60	11.20	**59.93 %**	**<.00001**

Parameters	**Control Group** (n = 5)				
	T1	**T2**	**Mean change**	**Percentage Mean change**	***P*-value**
CARS	33.90 ± 1.24	30.30 ± 3.68	3.6	**10.62 %**	.0625
SA	21.41 ± 5.44	32.60 ± 8.24	11.19	**52.27 %**	**.0625**
SQ	49.13 ± 5.45	58.77 ± 14.73	9.64	**19.62 %**	**.125**
DA	28.30 ± 6.69	41.00 ± 7.04	12.7	**44.88 %**	**.0625**
DQ	65.60 ± 11.68	72.97 ± 7.22	7.37	**11.23 %**	**.1875**
RLA	19.60 ± 7.13	26.40 ± 9.53	6.80	**34.69 %**	**.10035**
ELA	16.80 ± 4.60	23.60 ± 6.23	6.80	**40.48 %**	**.05447**

Supplementary Files

Figures

Challenges in providing therapy to individuals with ASD.



The technologies and features in the software.

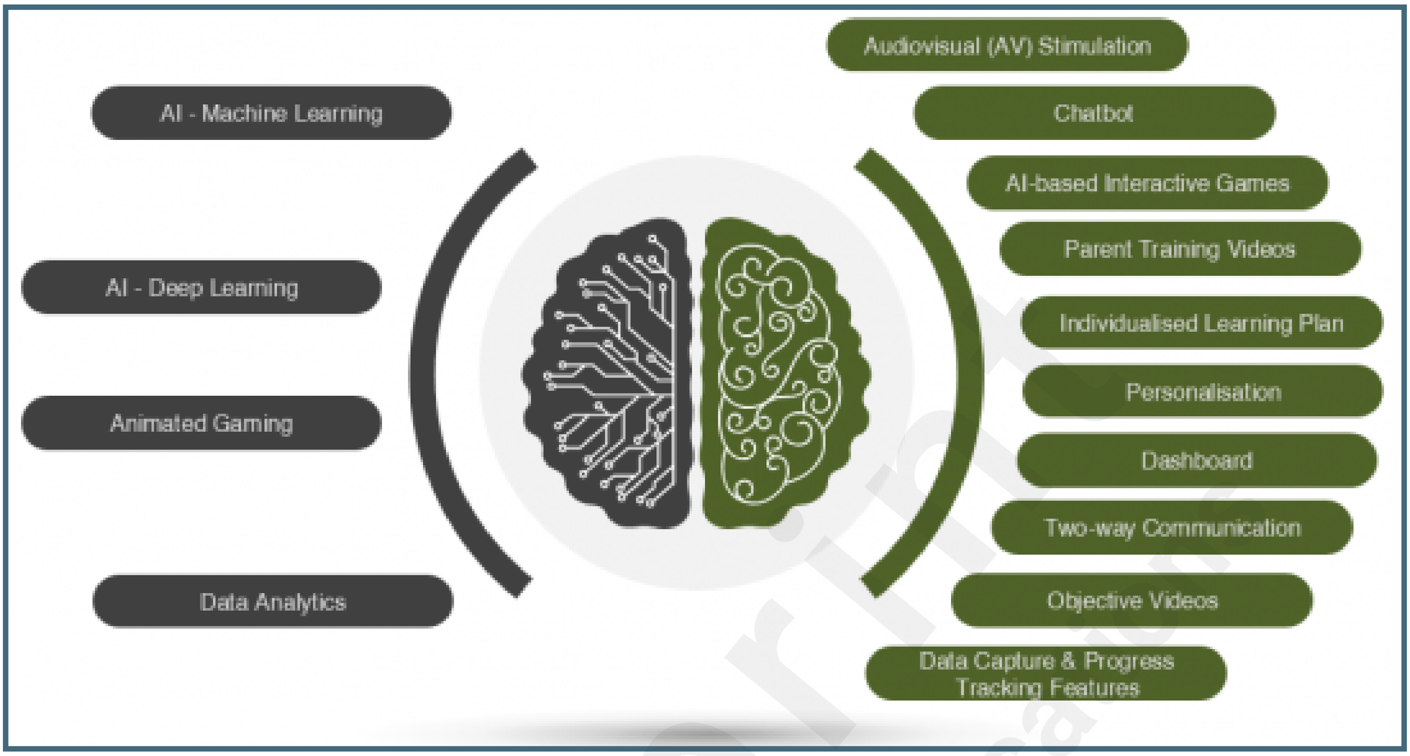
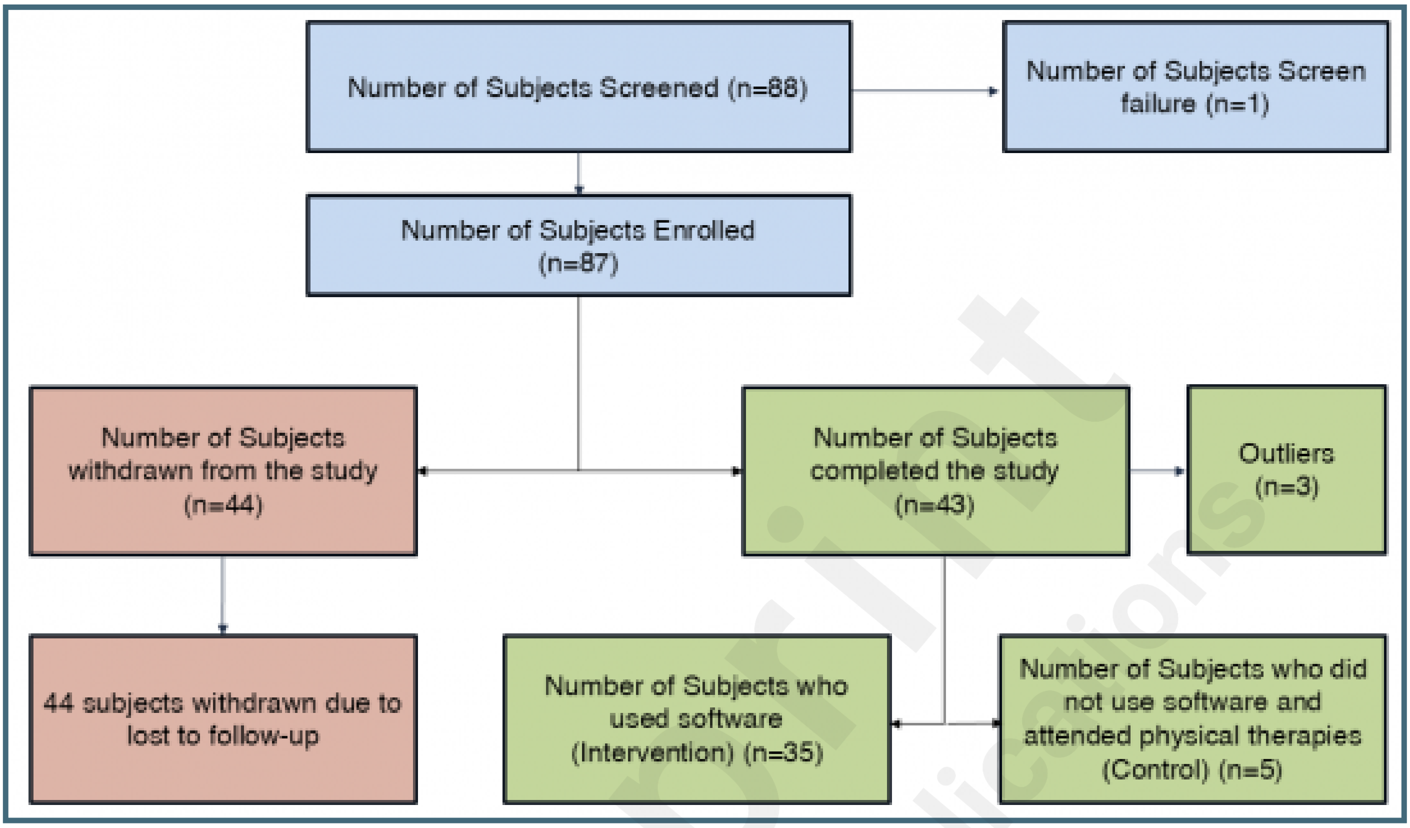


Fig 3.A screenshot of a lesson and the transcript of child-software interaction.

Flowchart of subjects in the study.



Related publication(s) - for reviewers eyes onlies

CSR Prospective study.
URL: http://asset.jmir.pub/assets/f6a8c246d7dc422b8601f8fd69b63032.pdf