Journal of Autism and Developmental Disorders
https://doi.org/10.1007/s10803-021-05101-w

BRIEF REPORT

Brief Report: A Novel Digital Therapeutic that Combines Applied Behavior Analysis with Gaze-Contingent Eye Tracking to Improve Emotion Recognition in Children with Autism Spectrum Disorder

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Accepted: 19 May 2021

Abstract
This study examined the feasibility, acceptability, and efficacy of a video game-based digital therapeutic combining applied behavior analysis techniques and gaze-contingent eye tracking to target emotion recognition in youth with autism spectrum disorder (ASD). Children aged 4–14 years with ASD were randomized to complete Lookware™ ($n = 25$) or a control video game ($n = 29$). Results from a 2 × 2 mixed ANOVA revealed that children in the intervention condition demonstrated significant improvements in emotion recognition from pre- to post-intervention compared to children in the control condition, $F(1,52) = 17.48$, $p < 0.001$. Children and staff perceived high feasibility and acceptability of Lookware™. Study results demonstrated the feasibility, acceptability, and preliminary efficacy of Lookware™.

Keywords Autism spectrum disorder · Emotion recognition · Applied behavior analysis · Gaze-contingent eye tracking · Digital therapeutic · Video game

Autism spectrum disorder (ASD) is characterized by deficits in social communication and interaction, as well as restricted repetitive patterns of behavior, interests, or activities (American Psychiatric Association, 2013). Children with ASD display deficits in emotion recognition (ER), which is the ability to identify emotions in themselves and others (Baron-Cohen et al., 1985, 1986). Emotion recognition is a crucial part of social development and viewed as a basic ability that underlies more complex emotional understanding and social skills (Jones et al., 2011). Facial emotion recognition

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Published online: 01 June 2021

(FER) may be utilized in analyzing the environmental cues related to emotional behavior, and eye tracking studies have consistently supported deficits in FER in youth with ASD across various emotional expressions (e.g., anger, sadness, happiness, fear; Harms et al., 2010; Lozier et al., 2014). The ability to visually scan the face in its entirety is imperative to teaching discriminations of facial cues within an emotional context. Individuals with ASD tend to focus on less emotionally expressive or relevant portions of the face, such as greater emphasis on scanning of the mouth rather than the eyes or upper portions of the face (Corden et al., 2008; Neumann et al., 2006; Spezio et al., 2007). This has important implications for ER as increased gaze directed at the eyes or decreased gaze at areas outside the mouth and eyes has been related to better ER among youth with ASD (Bal et al., 2010).

Effective behavioral interventions exist for the remediation of social skill deficits in children with ASD. Behavior analytic therapeutic approaches for improving social skills and ER, such as discrete trial training (DTT), video modeling, and peer-mediated instruction are considered effective interventions (Matson, 2009). Naturalistic Developmental Behavioral Interventions (NDBIs) that utilize naturalistic play environments to deliver interventions combining behavioral and developmental principles have also been demonstrated to be effective and offer advantages for the generalizability of some skills (Schreibman et al., 2015). The main instructional challenge with these approaches is the need for intensive teaching and for vast numbers of learning opportunities. This requires significant time from trained professionals with specialized expertise who are often not accessible due to a shortage of supply (Behavior Analyst Certification Board, 2019). Thus, it is imperative to identify approaches that serve as augmentative treatments to improve ER. Specifically, approaches that can be administered semi-autonomously, with less time and supervision required, resulting in efficacy and resource advantages.

Video game platforms as a digital therapeutic help overcome these barriers and are gaining popularity as an effective and empirically-supported means of augmenting behavioral interventions for children with ASD and other neurodevelopmental disorders (e.g., Kollins et al., 2020; Yerys et al., 2019). The Food and Drug Administration (FDA) recently cleared the first prescription-only game-based digital device for treatment of attention deficit hyperactivity disorder, a neurodevelopmental condition (FDA, 2020). Computer games targeting improvement in facial recognition using didactic instructions and lessons, imitation exercises, repeated practices, and quizzes or games matching emotional depictions, have resulted in improvements in ER, facial recognition, and social interactions (e.g., Hopkins et al., 2011; Lacava et al., 2010; Rice et al., 2015; Russo-Ponsaran et al., 2016; Weigner & Depue, 2011). The structured repetition, discreteness, and focus on specific components of complex skills in DTT approaches may make these types of behavioral interventions particularly suitable for delivery via gaming platforms.

However, these gaming platforms have not largely implemented gaze-contingent eye tracking (GCET) which would allow for immediate reinforcement of successive approximations toward the terminal behaviors (e.g., targeted visual behaviors including facial scanning). Without this specific and precise gaze data, an intervention cannot measure or reinforce these gaze behaviors that are necessary for building ER skills. One training program that used GCET to trigger events designed to increase attention to faces presented in a video produced encouraging findings among 3-year-old children with ASD (Wang et al., 2020). Use of GCET embedded in a gaming platform may create a potent reinforcement mechanism for desired gaze behaviors in this population given nearly half of youth with ASD choose to use electronic or computer games during their free time (Mazurek et al., 2012). This reinforcement mechanism also allows pairing a non-social reinforcer (video games) with socially mediated instruction, which may establish social learning as a reinforcing activity.

In response to the need for an accessible intervention to promote ER and the potential for video game platforms to serve as an efficient and acceptable intervention for children with ASD, BioStream Technologies, LLC developed a digital therapeutic in the form of an immersive 3D video game-based training platform combining GCET with instructional techniques of Applied Behavior Analysis (ABA) including DTT, shaping, and differential reinforcement. These commonly accepted techniques are used in the deployment of novel ABA-based therapeutic exercises using GCET that are designed to drive positive changes in visual behavior and attention in children with ASD, targeting core social skills deficits including eye contact and ER. Game performance is controlled in part by the child's visual behavior; gaze data is immediately captured and processed in near real time to prompt, differentially reinforce, and shape targeted gaze behaviors. The game is designed to be administered semi-autonomously. An initial pilot efficacy trial (cf. NSF Award ID #1747058) demonstrated the ability of children with ASD to independently use the platform and generated encouraging data on its ability to improve eye contact and ER in children with ASD.

The current study examined the feasibility, acceptability, and efficacy of Lookware™ in a larger, multisite, double-blinded randomized controlled trial. We hypothesized that the platform would be (a) efficacious for improving ER in children with ASD and (b) perceived as feasible and acceptable by children and their treatment providers (i.e., teachers, therapists).

Method

Participants

Participants were 54 children aged 4–14 years ($M_{age}=8.56$, $SD=2.84$ years; 87% male) with ASD. Inclusion criteria were: (a) documentation of an ASD diagnosis from a licensed medical professional; (b) English as primary language; (c) prior use of a video game platform (i.e., to ensure participants knew how to use video game controllers); (d) either parent-reported difficulty in maintaining eye contact with others, or difficulty understanding others' facial expressions as evidenced by a raw score of no greater than 45 on the Ekman-60 (Ekman, 1976); and (e) a standard score greater than 40 on the Peabody Picture Vocabulary Test (PPVT-4; Dunn & Dunn, 2007). Children were excluded from the study if they had: (a) a history of seizures; (b) a traumatic brain injury or other neurological disorder; (c) a visual impairment unable to be corrected to at least a level of 20–40 in both eyes; (d) an auditory impairment that could not be corrected with a hearing aid; (e) a history of psychiatric hospitalization; or (f) a DSM-5 diagnosis that would significantly interfere with participation (e.g., psychotic symptoms, conduct disorder). Participants were recruited on a rolling basis using flyers and participant or staff referrals in the community and across six schools and therapy centers located in four US metropolitan areas.

Study Conditions

Intervention

Lookware™ is a digital therapeutic delivered through a consumer grade laptop computer, low-cost Tobii 4C eye tracker, and Xbox game controller. The user is not required to wear any sensors or devices. The platform is designed to be used independently by a large segment of children with ASD without significant involvement of therapists, educators, and parents. ABA-based therapeutic exercises using GCET are embedded in an immersive 3D video game that captures eye-tracking data in millisecond intervals relative to the targeted visual behavior of the child. It processes this data in near real time to adapt the child's game experience seamlessly and programmatically through the introduction of different forms of guidance and reinforcement, and exercise difficulty level is adjusted based on child performance. In these ways, the platform intelligently adapts to each child to maintain him or her in a training zone where they are consistently challenged, but not overwhelmed, and enables gradual shaping of targeted behaviors. The game uses auditory and visual prompts (both stimulus and response), some of which are gaze-contingent, to encourage the player to look at specific emotionally expressive areas of the face which builds on the understanding that individuals with ASD focus on individual facial features when performing ER tasks (Rutherford & McIntosh, 2007). In this way, the platform teaches in a way that closely aligns with current understanding of the different ways in which ER learning occurs in children with ASD. During each session, the platform captures the child's game performance data, including exercise difficulty level attainment and discrete trial success rate, and transmits this data via the internet to a secure cloud-based server where on-demand exercise progress reports can be delivered to therapy and education providers.

Gameplay sessions are comprised of a therapeutic exercise phase and a reward phase that cycle back and forth several times during each session. In the therapeutic exercise phase, the child engages in discrete trials (i.e., repetitions) of gaze-controlled exercises delivered in succession during simulated social interactions with 3D animated cartoon characters. Prior research has supported that cartoon character depictions may support greater improvements in ER in youth with ASD than photographs of real faces (Vasilevska Petrovska & Trajkovski, 2019). During game exercises, children are prompted to, and receive reinforcement for, focusing their gaze on the eye and mouth regions of game characters and engaging in an emotion matching task. The degree of emotion expression is maintained across images so as to ensure key facial characteristics of each emotion are clearly visible. Gaze pattern data is collected for eye and mouth regions as well as several additional regions of the game character's face. If the child has difficulty with the exercise task, the game automatically reduces the exercise difficulty level. A token economy is used to provide differential reinforcement; the more accurate the child's exercise performance, the more tokens received, which can later be used to unlock special powers in the reward phase. In the reward phase, the child enters a virtual video game arcade of different mini-games from which to choose. Following completion of the selected mini-game, the child returns to the therapeutic exercise phase. The frequent cycling of these phases provides a high degree of saliency between exercise performance and reinforcement, minimizes exercise fatigue, and maintains child engagement over time. This enables delivery of an exponential increase in the number of learning opportunities with machine-based consistency and precision.

Control

Participants in the control condition engaged in a video game that included the same mini-games and used the same electronic materials (e.g., laptop, eye tracker, game controller) as the intervention; however, it did not include the intervention's therapeutic exercises.

Procedure

Study procedures received Institutional Review Board approval. The CONSORT flow diagram in Fig. 1 presents complete participant screening and enrollment information. Families were contacted by phone and screened on initial inclusion criteria (e.g., parent-report of ASD diagnosis, English speaking, prior video game use with a game controller) and exclusion criteria (e.g., sensory-motor difficulties or severe intellectual disability that would preclude use of a computer or mobile computing device). Qualified participants attended an in-person screening to verify additional inclusion criteria; documentation of an ASD diagnosis from a licensed medical professional, and the PPVT-4 and Ekman-60 were conducted to verify inclusion criteria for verbal intelligence and current ER deficits. Evidence suggests that the PPVT-4 correlates strongly with verbal IQ and is a less time-intensive proxy for obtaining information on verbal IQ (Krasileva et al., 2017).

After completing screening, children were randomly assigned to either the intervention ($n = 25$) or control ($n = 29$) condition. Participants engaged in video gameplay at either their school ($n = 30$), therapy center ($n = 21$) or home ($n = 3$). The individual overseeing participant gameplay

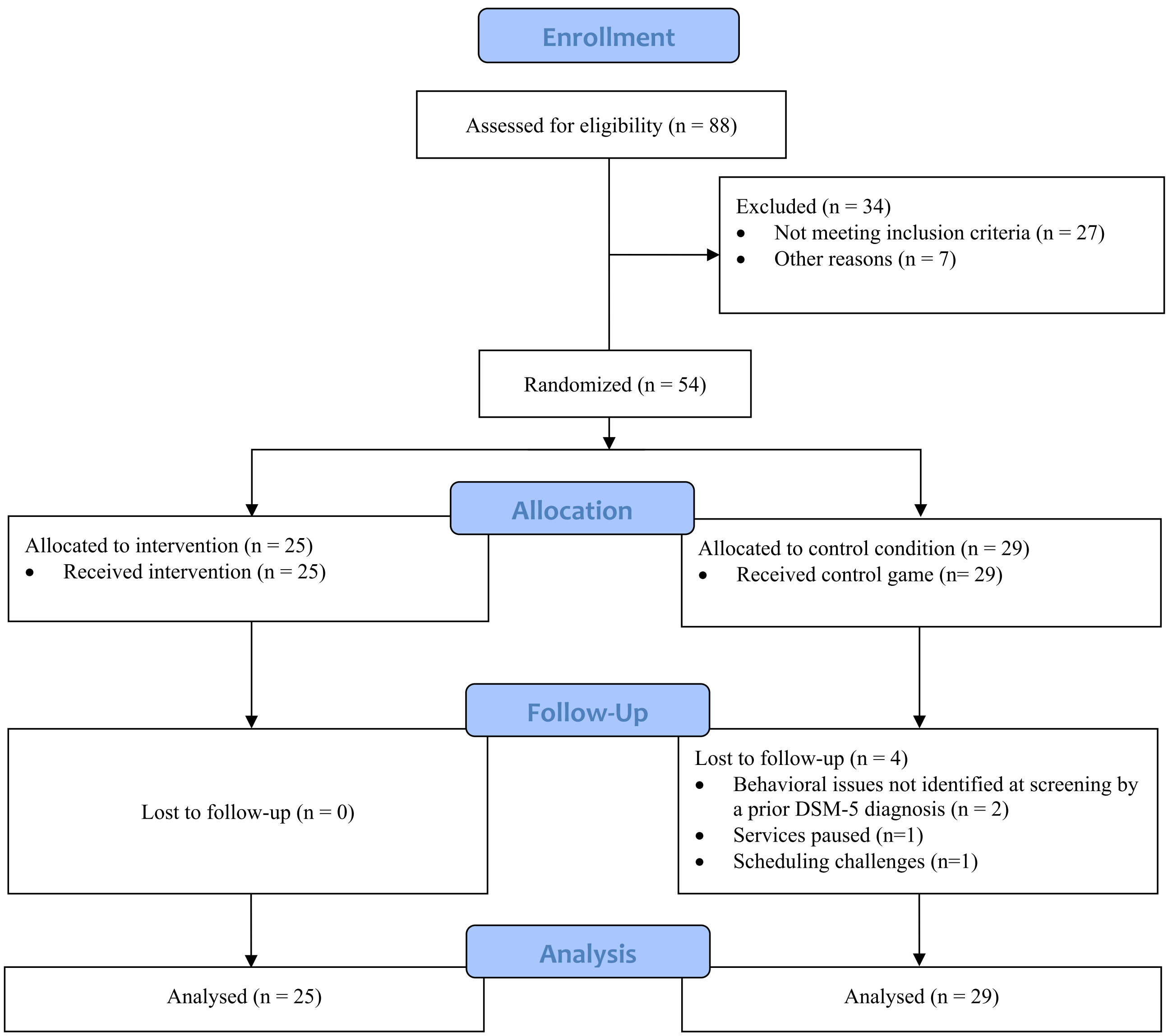

Fig. 1 CONSORT flow diagram

(i.e., monitor) received training on how to operate the platform and follow the study protocol. Over approximately six weeks, participants engaged in three to five game sessions per week, with at least 15 min of gameplay required for a session to be counted. Participants, monitors, assessment administrators, and staff completing measures were blinded to group assignment. Participants received a $50 gift card.

Outcome Measure

Emotion Recognition

Children's ER was assessed using the electronic Ekman-60. The Ekman-60 has been well validated and used as an objective and unbiased measure of ER, including in children with ASD (Lawrence et al., 2015; Trevisan & Birmingham, 2016). Ekman photos have also been used to assess treatment response to interventions targeting social cognition and ER in participants with ASD (Didehbani et al., 2016; Kandalaft et al., 2012; Lacava et al., 2010; Williams et al., 2012). The Ekman-60 consists of the presentation of 60 faces across 10 actors presenting six basic emotions (i.e., happiness, anger, sadness, fear, surprise, disgust). Facial expressions are displayed on the computer for five seconds, after which the image disappears, and participants select from a list of emotions which best described the facial expression shown. Scores range from 0 to 60, with higher scores indicating more correct responses. Children completed the Ekman-60 in-person at baseline, midpoint (i.e., ~ 3 weeks), and post-intervention (i.e., ~ 6 weeks); in the event that baseline scores were not available, Ekman-60 scores from the participant's in-person screening were used as the baseline score. Post-intervention Ekman-60 assessments were conducted, on average, two days after the final treatment session ($M = 2.26$, $SD = 4.25$ days). We sought to examine primary outcomes from baseline to post-treatment, and therefore only data from baseline and post-treatment were used in the current analyses.

Surveys of Research Staff and Study Participants, Social Validity Measures

Research Site Staff's Perceptions of Lookware™

At the conclusion of the study, a staff member (i.e., one therapist or teacher) at each research site, who had regular interaction with the study participants, completed a survey about feasibility, acceptability, and an overall evaluation of the platform. Staff rated statements related to acceptability and feasibility of the platform ranging from 0 ("*Never true*") to 6 ("*Always true*"). Acceptability was assessed using the statement, "*The participant seemed to enjoy the game*." Feasibility was assessed using the statements, "*The participant understood the game.*" and *"The participant was able to navigate the game using the game controller and was able to independently do the required tasks.*" Staff also rated their overall evaluation of the platform and its value in helping teach ER, eye contact, and attention on scales ranging from 0 ("*Never*") to 6 ("*Always*"), 0 ("*Not at all valuable*") to 6 ("*Extremely valuable*"), or 0 ("*Not at all*") to 6 ("*Very significantly*"). Statements used to assess overall evaluation of the platform are presented in Table 1. Rating responses above "*Neutral*" (e.g., *Sometimes true*," "*Usually true*," "*Always true*") were combined to determine the percentage of positive responses.

Study Participant's Perceptions of Lookware™

Child perspective of platform feasibility was assessed at the end of the study using the following questions, "*Was it hard to understand how to play the game?*" (response options: "*Yes*," "*A little bit*," "*No*.") and "*How easy was the game today?*" (response options: "*Hard*," "*Medium*," "*Easy*"). In each case, the latter two response options were combined to assess the percentage of participants where feasibility was demonstrated. Acceptability of the video game was assessed at the end of the study with the question, "*How did you like playing the video game today?*". The response options were, "*I didn't like it*," "*I liked it*," and "*I liked it a lot*." The latter two responses were combined to determine where acceptability of the game was demonstrated.

Analytic Strategy

Analyses were conducted using IBM SPSS Statistics (Version 27) software. Data were assessed for normality and outliers, and the intervention and control groups were compared at baseline on demographics, PPVT-4 scores, and the outcome measure to ensure group equivalency. No significant differences were found in age, gender, Ekman-60, or PPVT-4 scores between groups at baseline, and no outliers were detected for baseline Ekman-60 scores; all data were approximately normally distributed. An intent-to-treatment approach was used as part of the a priori analytic plan. We used last observation carried forward (LOCF) to impute missing values for the four participants who were lost to follow-up after the baseline Ekman-60 assessment. This imputation method was used given the small amount of missing data and lack of auxiliary data (e.g., IQ, symptom severity) to generate accurate values that account for the missing data pattern in more sophisticated, stochastic imputation methods (e.g., multiple imputation; Schlomer et al., 2010). A 2 (Time) × 2 (Condition) mixed ANOVA was conducted to test

Table 1 Perceptions of the intervention and its acceptability and feasibility

Survey question	n (% favorable response)
Acceptability of Lookware™	
Study participant:	
How did you like playing the video game today?	20 (100%)
Staff:	
The participant seemed to enjoy the game.	12 (83%)
Feasibility of Lookware™	
Study participant:	
How easy was the game today?	19 (95%)
Was it hard to understand how to play the game?	8 (40%)
Staff:	
The participant understood the game.	12 (83%)
The participant was able to navigate the game using the game controller and was able to independently do the required tasks.	12 (83%)
Perceptions of Lookware™ and Participant Behaviors	
Staff:	
Based on my observations, I would recommend this game to another teacher/therapist.	13 (92%)
I believe this game was valuable to the participant for the purpose of helping to teach the importance of eye contact.	15 (73%)
I believe this game was valuable to the participant for the purpose of helping to teach the importance of recognizing the emotions of others.	15 (80%)
I believe this game was valuable to the participant for the purpose of helping increase attention skills.	15 (60%)
I believe this game has increased the participant's social awareness.	15 (67%)
I believe this game would be an important addition to the treatment package the participant has in place for helping to build his/her social skills.	14 (71%)
I believe this game has potential for helping social skill development for other participants like this participant.	15 (73%)

"Favorable responses" refer to those responses above "*neutral*" on a 7-point Likert scale. The sample size for each item reflects available data drawn from the intervention sample ($n = 24$) across six research sites. One intervention participant whose data was collected in the home did not have a staff member complete a survey and thus was excluded from these analyses

for between-group differences in Ekman-60 scores from pre- to post-intervention. If a significant interaction was detected, results were plotted with a bar chart. Cut-offs for interpreting effect sizes (i.e., η^2) were based on suggestions provided by Cohen (1988): small = 0.01, medium = 0.06, large = 0.14.

Results

Significant Condition × Time Interaction

Results from the 2 × 2 mixed ANOVA revealed a significant Condition x Time interaction, $F(1,52) = 17.48$, $p < 0.001$, partial $\eta^2 = 0.25$). As can be seen in Fig. 2, participants in the intervention condition demonstrated significant increases (i.e., ~ 25% change) in their Ekman-60 scores from pre- to post-intervention, whereas there was no evidence of change among participants in the control condition. Means, standard deviations, and ranges for Ekman-60 scores by group, across time, can be seen in Table 2. Although qualified by the significant interaction, we detected a main effect of time, $F(1,52) = 28.38$, $p < 0.001$, partial $\eta^2 = 0.35$, such that Ekman-60 scores increased from pre- to post-intervention. There was no evidence of a main effect of the intervention condition on Ekman-60 scores, $F(1,52) = 0.76$, $p = 0.39$, partial $\eta^2 = 0.01$).

Table 3 presents descriptive data for demographics and outcome variables. Participants engaged in an average of 3.12 ($SD = 0.76$) sessions per week and 6.41 ($SD = 1.89$) total hours of gameplay over the course of the study. The number of sessions per week and total hours of gameplay were similar across conditions ($ps > 0.05$). Children in the intervention group engaged in an average of 577.84 discrete trials throughout the study period ($SD = 170.5$, range 290- 892).

Regarding the feasibility and acceptability data, all children in the intervention condition who responded to the

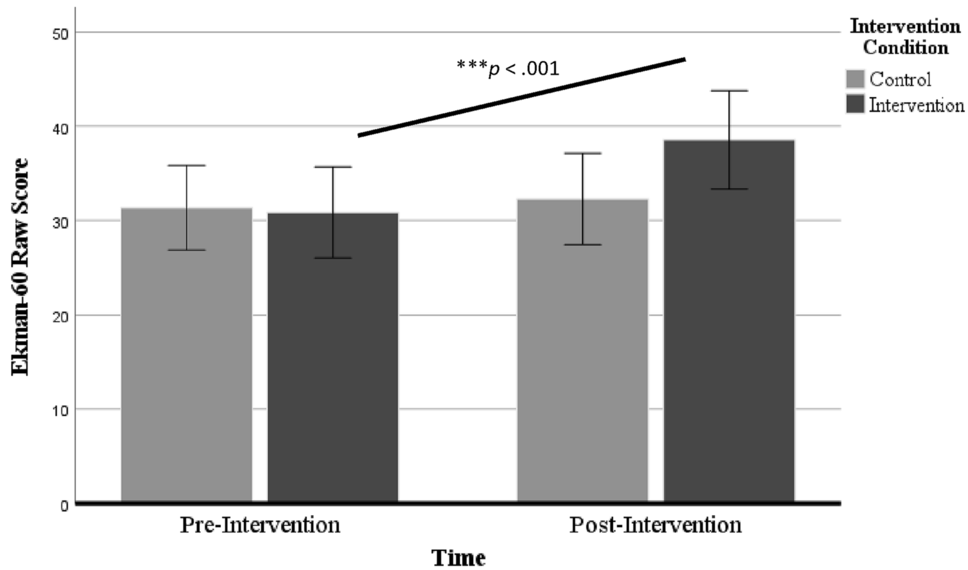

Fig. 2 Intervention condition × time interaction

Table 2 Ekman-60 scores by study condition

Timepoint	Intervention Mean (*SD*), range	Control Mean (*SD*), range
Baseline	30.84 (*10.90*), 10–47	31.34 (*12.94*), 9–50
Post-treatment	38.56 (*12.66*), 10–59	32.28 (*13.32*), 9–50

The values above reflect the significant condition by time interaction, $F(1,52)=17.48$, $p<0.001$, partial $\eta^2=0.25$

acceptability question ($n=20$) indicated they "*Liked*" the game or "*Like it a lot*." All children also responded favorably to the feasibility questions, with 60% ($n=12$) reporting that they understood the game and 95% ($n=19$) reporting the game was easy (see Table 1). Among research site staff's reports on 12 intervention participants, 83% ($n=10$) indicated that they thought the child enjoyed and understood the intervention and that the child was able to independently perform the required tasks of the intervention. The majority of staff felt that the game was valuable for teaching and/or improving the participants' ER, eye contact, social skills, and attention (see Table 1). Nearly all staff (92%) indicated that they would recommend the game to another teacher/therapist.

Discussion

The current study tested the feasibility, acceptability, and efficacy of the first video game-based digital therapeutic developed specifically for youth with ASD using ABA techniques and GCET to target improved ER. Lookware™

Table 3 Demographic and baseline data

	Full sample ($N=54$) M (*SD*)	Intervention group ($n=25$) M (*SD*)	Control group ($n=29$) M (*SD*)
Participant age	8.56 (*2.84*)	7.88 (*2.37*)	9.14 (*3.11*)
Participant gender (% male)	87%	96%	79%
Baseline Ekman-60	31.11 (*11.93*)	30.84 (*10.9*)	31.34 (*12.94*)
Baseline PPVT-4	86.88 (*17.42*)	87.5 (*15.41*)	86.33 (*19.30*)
Extremely low	10	5	5
Moderately low	13	5	8
Average	26	14	12
Moderately high	1	0	1
Extremely high	1	0	1

Although not an outcome measure, PPVT-4 scores are presented to demonstrate group equivalency in verbal intelligence. The categories presented reflect clinical cut-offs based on an average standardized score of 100 and a standard deviation of 15. The PPVT-4 was completed by all participants, but scores are unavailable for three participants demonstrated a large effect for improving objectively measured ER. Furthermore, this effect was achieved with only approximately six hours of gameplay, and implementation of the program did not require significant involvement of trained professionals. These results are consistent with prior evidence that technology-based interventions contribute to improvements in ER in children with ASD (Kouo & Egel, 2016). Notably, the game was demonstrated to be feasible, acceptable, and efficacious in a sample of children with a range of verbal intelligence abilities, suggesting the game may be generalizable and appropriate for children of varying levels of functioning. All children who engaged with the game reported that they enjoyed the game, and nearly all children reported that the game was easy. While eight children reported the game was hard to understand, the fact that nearly all participants also reported that the game was easy is consistent with presentation of a novel GCET-based game that challenged them to learn a new skill. The majority of staff at the research sites reported that children appeared to enjoy and understand the game, were able to independently perform its required tasks, and nearly all staff would recommend the game to other professionals. This RCT provides preliminary support for Lookware™ as a means for improving ER in youth with ASD.

Results suggest that the evidence-based techniques of ABA (e.g., DTT, differential reinforcement, prompting) can be efficaciously implemented through a game-based digital therapeutic with embedded GCET, requiring fewer resources than typical ABA instruction. The intervention was able to provide approximately 600 discrete learning trials (which included presentation of an average of over 2,000 faces) with machine-based accuracy and consistency, during only approximately six hours of gameplay. The ability of Lookware™ to provide a large number of discrete learning trials efficiently may allow for more rapid acquisition of ER skills when used as supplemental reinforcement to ABA, where the number of learning opportunities is constrained by the manual and time-consuming nature of instruction and involvement of a certified clinician such as a Board Certified Behavior Analyst (BCBA).

Lookware™ provides instruction and prompts the learner to attend to faces thereby increasing opportunities to gaze at and respond to faces with different emotions, which research has shown may affect ER skill development (Gauthier et al., 2000). Using GCET, the game delivers immediate conditioned positive reinforcement for gaze directed at key areas of the face for ER (e.g., eyes), areas that individuals with ASD are known to observe less (Corden et al., 2008; Neumann et al., 2006; Spezio et al., 2007). This contingency may be particularly reinforcing for youth with ASD given high rates of computer and electronic gameplay in this population (Mazurek et al., 2012) and may demonstrate greater effects for achieving desired behavior than rewards and consequences used in many other treatments, such as verbal reinforcement. Next steps in our research include examining the gaze pattern data to understand the mechanisms that underlie achievement of the positive behavioral changes noted in ER among intervention participants. Future iterations of the platform also will explore weighted or targeted GCET based on the relative importance of different regions of the face in recognizing specific emotions.

The results from the present study should be considered in light of several limitations. First, the PPVT-4 was administered to serve as a proxy for verbal IQ, but no further intelligence testing (e.g., Wechsler Intelligence Scale for Children-V) was conducted; therefore, we are not able to provide a comprehensive description of cognitive functioning of our participants. Relatedly, although documentation of an ASD diagnosis from a licensed medical professional was required for study inclusion, no additional assessment (e.g., ADOS-2, ADI-R) was administered to confirm a diagnosis of ASD in study participants. The lack of an independent ASD assessment did limit our ability to examine the role of ASD symptom severity in relation to the intervention. However, while completion of the ADOS-2 may be a research gold standard, our study intended to be an effectiveness study and represent real-world conditions where completion of the ADOS-2 is not completed with all patients. Another study limitation was the differential dropout across study conditions, such that only children assigned to the control arm were among those who were lost to follow-up. This number was small ($n = 4$) but presents a potential bias in our findings. Relatedly, these missing values for post-intervention follow-up were handled using the last observation carried forward (LOCF) imputation method. Although this method has the potential to introduce bias, the overall missingness was minimal and additional covariate data were not available (e.g., IQ) that would allow us to account for the missingness pattern and effectively implement more sophisticated imputation methods (e.g., multiple imputation). Lastly, our sample size prevented meaningful moderation analyses to determine whether child characteristics such as age, sex, or symptom severity moderate treatment effectiveness. The Ekman-60 findings, in addition to the feasibility and acceptability data, suggest promising utility of Lookware™ across a wide age range, and these treatment moderators should be explored in larger trials.

Future research should examine use of Lookware™ with a larger and more diverse sample. All children in the current study had previously used a video game platform, and research should examine whether children without prior use of video games are able to understand and benefit from Lookware™. The extent to which benefits following ER training are generalized to social settings among people with ASD is largely unknown (Berggren et al., 2018). While the staff-reported social validity data from this study suggests

ER skills generalizability, additional study is needed to identify whether the improvements from Lookware™ translate to real-life social situations and improve social functioning.

Preliminary research with Lookware™ has shown that a digital therapeutic using GCET can effectively increase ER in children with ASD and can provide accessible instruction with minimal resources. While this intervention is not intended to serve as a substitute for traditional ABA instruction with a clinician, Lookware™ has the ability to be easily implemented as an augmentative treatment reinforcement for youth receiving ABA to support additional DTT learning opportunities and to enhance speed of skills acquisition. This implementation is feasible given the intervention can be delivered without the need for significant time of trained personnel and in a variety of settings with minimal technology needed. The game may also be an alternative for youth who are unable to receive ABA treatment due to lengthy waitlists, the shortage of BCBAs, insurance coverage barriers, or access to in-person intervention. The options for telehealth and virtually accessible services for youth with ASD are currently limited, which may create significant barriers to treatment for youth living in rural communities or in situations where social distancing is required (e.g., virus pandemic). The combination of established ABA techniques with precise eye-tracking technology and incrementally and immediately dosed and adjusted therapeutic interventions delivered through an accessible, acceptable, and feasible video game may provide an avenue for closing the gap in care for underserved families and to reinforce skills acquisition in children receiving ABA.

Acknowledgements We would like to thank the children and members of their family who gave their time and effort to participate in this study. The study was sponsored by BioStream Technologies, LLC. We would also like to thank the following individuals and organizations for their participation in the study: David Sides, Philadelphia, PA, Amy Golden, Cherry Hill, NJ, Mary E. Keefe, Point Pleasant Beach, NJ, Y.A.L.E. School, Cherry Hill, NJ, Partners in Learning, Inc., Williamstown, NJ, Els for Autism Foundation, Jupiter, FL, Nashoba Learning Group, Inc., Bedford, MA, Positive Behavior Supports Corporation, Stuart, FL, The Pathway School, Jeffersonville, PA, Christopher Hoopes, Wilmington, DE, Justin Patterson, Alexandria, VA, Bhupinderjit Dhanoa, Voorhees, NJ, and Grant Ervin, Raleigh, NC.

Author Contributions MJW and MAF jointly conceived and designed the study. MJW and MAF enlisted the support of different research sites. DWS conducted the data analyses with input from COS and COS drafted the manuscript with input from DWS, MJW, TC, AC, AF, ME, JW, SAF, and MAF. All authors read and approved the final manuscript.

Funding This study was sponsored by BioStream Technologies, LLC. The company provided financial support in the form of payment to the following research sites for work performed on the study: Mary E. Keefe, Partners in Learning, Inc., Els for Autism Foundation, and Positive Behavior Supports Corp.

Declarations

Conflict of interest Authors DWS and COS are consultants of BioStream Technologies, LLC and received monetary compensation from the company for the work performed for the study. TC, AF, and ME were employed by a research site that received funding from BioStream Technologies, LLC to conduct the research. SAF is a consultant of BioStream Technologies, LLC and received a financial interest in the company for the work performed for the study. MJW served as an employee, and is currently a consultant, of BioStream Technologies, LLC. MJW received both monetary compensation from the company and a financial interest in the company for the work performed for the study. MAF has an indirect financial interest in BioStream Technologies, LLC.

Ethical Approval All procedures performed in this study with human participants were in accordance with the ethical standards of the institutional research board committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This included obtaining informed parental consent and child assent (as required) for all participants.

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