Experiences With Virtual Reality Based Therapy for Joint Attention: A Usability and Initial Feasibility Pilot of FloreoVR's Joint Attention Module in a Special Education School Setting

Introduction

Autism spectrum disorder (ASD) is a heterogeneous neurodevelopmental condition characterized by variable degrees of impairment in social communication and restricted and repetitive patterns of behavior (American Psychiatric Association, 2013).

While much attention has been paid to the pathogenesis and diagnosis of autism spectrum disorder, there remains a clear need for effective treatments for the core symptoms of ASD. Ideally, implementation of treatments during childhood will lead to optimal outcomes in adult life.

Educational costs can be substantial for children with ASD. With the national cost of supporting children with ASD in the United States estimated at $61 billion in total, special education expenses have accounted for a large percentage of this estimate (Buescher et al, 2014). Per year, the economic burden of addressing the healthcare and education needs of children with ASD has averaged more than $17,000 per child. Students with ASD incurred higher school costs than their peers without ASD (Lavelle, Weinstein, Newhouse, Munir, Kuhlthau, and Prosser, 2014).

Students with ASD require significant therapeutic support during their years in school. A survey of special education data noted that services included speech language therapy for 66.8% to 85.2% of autistic students, while 34.6% to 44.6% of students had behavioral services in place. This study noted that the significant number of students receiving speech language and occupational therapy was “consistent with the severity of communication impairments and with the pervasive effects of ASDs on activities of daily living” (Wei, Wagner, Christiano, Shattuck, and Yu, 2014).

Optimal outcomes have been described for children with ASD who have matured into young adulthood, with a percentage no longer meeting diagnostic criteria for ASD and having no significant differences in functional skills from peers without a history of ASD (Fein et al., 2013). Individuals with such optimal outcomes were noted to have milder social symptoms than others who maintained a high-functioning ASD profile into young adulthood.

Joint attention is a skill that involves responding to bids for attention as well as being able to initiate bids for attention. Older children with ASD and more developed language skills were noted to have shown better joint attention in early childhood (Sigman and Mc Govern, 2005). Conversely, impairment in joint attention in early childhood is related to limited language development by school age in children with ASD (Thurm, Lord, Lee, and New schaifer, 2007). Joint attention is seen as a pivotal skill for development of more advanced communication and social skills (Charman, 2003; Jones, Carr, and Feeley, 2006; Toth, Munson, Meltzoff, and
Dawson, 2006; Warreyn, van der Paelt, and Roeyers, 2014). The ability to initiate joint attention in children with ASD is related to enhanced social interaction competence (Travis, Sigman, and Ruskin, 2001). As such, joint attention has been studied as a target for interventions in children with ASD (Jones et al., 2006; Kasari, Freeman, and Paparella, 2006; Kasari, Gulsrud, Wong, Kwon, and Locke, 2010).

Given the increasing prevalence of ASD in the population, the impact of persisting deficits in social communication and daily living skills in adults with ASD, and the high societal costs associated with supporting individuals with ASD, it is critical to develop innovative means of delivering treatment to affected children. Advances in virtual reality technology offer new opportunities to design interventions targeting the core deficits associated with ASD and promote progress toward optimal functional outcomes.

Pilot studies by other researchers have been promising. Researchers at Politecnico Milano have done a pilot study using supervised low-cost VR via Google Cardboard on a small sample of five children with intellectual disabilities (Garzotto, Gelsomini, Clasadonte, Montesano, & Occhiuto, 2016; Gelsomini, Garzotto, Montesano, & Occhiuto, 2016). The results have been promising. The children in the study accepted the Google Cardboard head-mounted display, and therapists found the therapy easy to use and beneficial to their clients. The therapeutic content is a storytelling application that requires the user to maintain eye contact with a virtual character for the story to continue.

In another pilot study, 29 adults with ASD used a head-mounted display (Oculus Rift), first for 10 minutes, and then possibly for a longer session at a later date (Newbutt et al, 2016). While the content was not therapeutic, it was entertaining and offered similar physical effects to proposed theoretic content. 4 of the 29 discontinued use of the virtual reality headset due to unwanted side effects. These side effects included dizziness and tiredness.

Another recent study asked 3 children (ages 10-13) with ASD using a head-mounted display to improve social understanding and social skills (Cheng, Huang, & Yang, 2015). These participants used the VR-based therapy once a week for 6 weeks. All subjects completed all sessions, and therapists report that the treatment modality was motivating. All subjects showed improvement with regard to targeted behaviors at the end of the study.

Past clinical research has been performed using virtual reality therapy to treat anxiety disorders. Existing research compares VR exposure for social anxiety disorder to traditional in-vivo exposure (Bouchard et al., 2017). Both in-vivo and “in-virtuo” treatments were effective, but VR was much more practical for therapists. In another study, CBT treatment for panic disorder that included a VR component was as effective as traditional CBT treatment, but the therapy that included VR required fewer sessions (Vincelli et al., 2003).

VR treatment was as effective as traditional CBT for treatment of arachnophobia in children (St-Jacques, Bouchard, & Bélanger, 2010), although there was some concern that children were
more afraid of virtual spiders than real spiders. One way to address this concern is to let children know ahead of time what they are going to see in the virtual world, such as only characters of normal size, with no supernatural abilities.

Participants in a randomized, controlled trial who received VR-based exposure therapy for PTSD were helped more than those who received traditional PTSD treatments (McLay et al., 2011). PTSD symptoms were measured using the Clinician Administered PTSD Scale.

In all VR-based therapies, there is the potential for unwanted physical side effects from being in a virtual environment. These side effects are similar to motion sickness or simulator sickness and are often called cybersickness. Symptoms include dizziness, nausea, eye strain, and fatigue. Best practices for clinical trials involving VR-based therapy include informing users about potential risks, monitoring users as they use VR, informing users how to minimize side effects, and designing VR environments to prevent as many causes of sickness as possible.

In practice, VR therapy for anxiety disorders involves limited amounts of VR exposure spread out over a suitable length of time, and side effects are not a problem for most patients. However, it should be noted that individuals with autism often have co-morbid sensory processing disorders, which can increase or decrease the likelihood of unwanted side effects. Newbutt et al. found that only 4 of their 29 participants with ASD dropped out due to cybersickness (Newbutt et al. 2016).

Most research on VR-based treatment for anxiety disorders involves adults and not children. Children have a hypothetical risk of maladaption to a virtual environment while their vision is still in a critical period. This hypothetical risk is only a factor when children stay in VR environments for very long periods of time, such as multiple hours spent playing VR video games. Short VR sessions for therapy pose very little risk.

Objectives

The primary objective of the pilot was to demonstrate feasibility of using the Floreo Joint Attention Module to train joint attention skills in a virtual reality setting in students with autism spectrum disorder attending a special education school. Safe use, potential adverse effects, and tolerability of Floreo’s VR software by school-age participants were of particular interest in conducting this pilot. A secondary objective was to assess feasibility of use of a novel joint attention measure for school age children to assess changes in participant joint attention skills over time. This was an open label pilot study with no control group.

Methods

Participants
Eligible participants were recruited at the Celebrate the Children school. Because this pilot study focused on the feasibility of using the Floreo Joint Attention Module as an educational intervention and an element of the normal summer camp curriculum at a special education school, it was deemed to be exempt from Institutional Review Board review. Instead, the initial pilot proposal was reviewed by an outside consultant with direct feedback incorporated in an edited and updated version of the protocol that was used for the pilot study.

Potential participants were identified by Celebrate the Children staff. Families were sent a SurveyMonkey questionnaire to collect demographic and health information in order to determine eligibility based on inclusion and exclusion criteria. SurveyMonkey, which was also used to collect pre-session and post-session information throughout the pilot, is HIPAA-compliant for confidential management of protected health information.

Inclusion criteria consisted of age between 7 and 18 years and diagnosis on the autism spectrum (or any diagnosis of autism spectrum disorder, Autistic Disorder, Asperger Syndrome, pervasive developmental disorder, or PDD-NOS). Exclusion criteria were history of seizures or known photosensitive response on EEG, migraines, vertigo or other serious balance disorder, or psychosis or other disorder disrupting the ability to distinguish reality from non-reality. In addition, families were also asked about their child's expressive communication level, augmentative and alternative communication techniques, prescribed and over-the-counter medications used, vision screening, problems with vision, use of corrective lenses, and history of problems with VR and 3D entertainment. All items in the screening questionnaire are listed in Attachment 1.

For informed consent procedures, parents of eligible participants were sent consent and assent forms via Docusign. A phone call was arranged to discuss the study with a parent and the eligible participant, in order to answer any questions and to obtain the participant’s assent. Parents and eligible participants sent back signed consent and assent forms through the confidential Docusign process. In addition to the consent and assent forms, families were also provided a child-oriented brochure, in comic book form, about virtual reality, how to experience it, and possible side effects (Attachment 2).

Treatment approach

The Floreo Joint Attention Module is software that offers a supervised virtual reality experience for individuals with ASD. Floreo provides a 3D immersive scene for Google Cardboard-compatible smartphones and a supervisory overview that can run on smartphones or tablets. To use the software, an individual with ASD places the smartphone into a Google Cardboard-compatible virtual reality (VR) headset, also known as a Head Mounted Display (HMD), and a monitor, who can be a therapist, teacher, or parent, guides and supervises the user on a device (tablet or smartphone) paired with the user’s device over a network connection.
The therapeutic content consists of a Joint Attention Module including separate Learning Cards addressing specific subskills necessary to develop appropriate joint attention behaviors. Each Learning Card consists of a virtual reality environment in a safari-themed setting, complete with animals designed to draw the student’s attention when necessary. Users proceed through Learning Cards sequentially in order to achieve set goals related to the demonstration of target joint attention subskills. An avatar in the virtual environment initiates and responds to joint attention bids, and can also verbally prompt the user when needed to make further progress through a Learning Card to achieve goals. The monitor tracks the student’s engagement and progress through each Learning Card and provides redirection and feedback as necessary.

In this pilot study, the Floreo Joint Attention Module was implemented in the special education setting by a school staff member working with a student during summer camp.

Participants engaged in one to two VR episodes per therapy session. Each VR episode lasted no more than five minutes, with a break in between the episodes of at least three minutes. Sessions occurred three days per week, with at least 48 hours between sessions. A total of fourteen VR sessions were completed over a five week period.

Floreo team members conducted training with designated monitors in preparation for the pilot study. This was done on-site at Celebrate the Children and included a presentation by Floreo team members as well as opportunities to practice using Floreo with feedback from Floreo staff. Objectives of the pilot, benefits of targeting and training joint attention skills, content of the Joint Attention Module Learning Cards, detailed instructions on use of the Floreo platform, and the overall structure of the intervention including pre- and post-session questionnaires were covered in the on-site presentation.

Prior to the first VR session, all participants underwent a joint attention assessment to capture their existing status of joint attention behavior. This assessment was a novel measure developed by the study team to directly assess joint attention skills in school-aged children (Attachment 3).

A review of the joint attention and social communication measure literature revealed several challenges with incorporation of existing measures in intervention research. At a high level, a recent review of social communication behavior measures that might be used for treatment endpoints in ASD found that there were no measures appropriate to use without conditions (Anagnostou, et al., 2015). Some of the measures reviewed were initially developed as screens for ASD-associated behaviors, such as the Social Responsiveness Scale (SRS) and the Autism Spectrum Rating Scales (ASRS). Other measures included in the review are broad in scope, assessing either adaptive behaviors as a whole, or a range of ASD-related behaviors, such as the Vineland Adaptive Behavior Scales (VABS), the Adaptive Behavior Assessment System (ABAS), the Pervasive Developmental Disorder Behavior Inventory (PDD-BI), and the Autism Diagnostic Observation Schedule (ADOS). The Communication and Symbolic Behaviors Scale (CSBS) and the Early Social Communication Scales (ESCS) are only appropriate for use in...
infants and toddlers, or young children with delayed communication skills. The CSBS in particular is only normed up to age 2.

Another recent review of approaches to assessment of minimally verbal school-age children with ASD found that measures addressing intentional communication “required high levels of expertise to code and interpret” or were “informal and nonstandardized” (Kasari, et al., 2013).

Of note, the Brief Observation of Social Communication Change has been developed, based off of social communication behaviors rated in the ADOS, and research is being conducted on its utility in clinical trials (Grzadzinski, et al., 2016).

Bean and Eigsti published a joint attention measure for school-age children and adolescents in 2012 (Bean & Eigsti, 2012), but the elements of this measure did not map well with the objectives of our Joint Attention Module. In addition, there has been no further research on this scale, and so the team made the decision not to use this particular measure.

For purposes of this initial pilot study, the team instead decided to develop a novel joint attention measure that could be administered quickly, included play-based activities appropriate for school age children, and focused on the key joint attention behaviors targeted in Floreo’s VR Joint Attention Module (Attachment 1). This measure is modeled after the joint attention measure found in the CSBS (Weatherby & Prizant, 2012). Our measure is geared toward teenage students with limited verbal skills and needs in social reciprocity. It is designed to measure instances of joint attention (specifically shifting eye gaze between a toy and a play partner) and uses age-appropriate appealing toys (cause and effect and sensory toys as well as one that allows for turn taking games. It should be noted that while we are measuring joint attention, this skill does not exist in a vacuum, but as a component of a socially reciprocal interaction, and so we are looking also at other features of social reciprocity. In scoring our measure, we look for instances of social reciprocity (initiating, responding, continuing conversation beyond two turns, commenting, questioning, requesting, protesting, and refusal), response to greeting as well as shifting eye gaze in response to a point, and instances of prolonged eye contact toward a person or an object. Notes are taken on affect and mood during video review.

This joint attention assessment was then repeated by the same examiner four weeks after VR sessions had concluded.

All VR sessions began with a greeting by the monitor, an employee of Celebrate the Children who was trained by Floreo staff to use the Joint Attention Module. Participants then completed a SurveyMonkey questionnaire, the “Pre-Session Check”, with written and visual components that inquired about general health status, balance, sleep, and interest in continuing with Floreo (Attachment 4). The monitor then set up the Floreo system on an iPad used by the monitor and a phone used by the participant inside the HMD. The HMD was cleaned if necessary. The
participant then put the HMD on and the monitor checked that the HMD had been put on correctly.

The first session consisted of one Learning Card episode to help participants orient themselves to the virtual reality environment. At subsequent sessions, participants were given the opportunity to engage in one or two VR episodes per session. Investigators were told to stop therapy if the participant appeared to be suffering any ill effects. Red flags for ill effects included preference for looking at the corners of the screen, change from standing to sitting or vice versa, fidgeting, changes in breathing pattern, sweating, or holding hands to the head. All sessions in the joint attention intervention pilot are listed in Table 1.

Table 1: Joint Attention Intervention Schedule

<table>
<thead>
<tr>
<th>Session 1</th>
<th>Learning Card 1</th>
<th>Explore</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 2</td>
<td>Learning Card 2</td>
<td>Who Made That Sound?</td>
</tr>
<tr>
<td>Session 3</td>
<td>Learning Card 3</td>
<td>Watch Me Go</td>
</tr>
<tr>
<td>Session 4</td>
<td>Learning Card 3</td>
<td>Watch Me Go</td>
</tr>
<tr>
<td>Session 5</td>
<td>Learning Card 4</td>
<td>Emma is Pointing</td>
</tr>
<tr>
<td>Session 6</td>
<td>Learning Card 4</td>
<td>Emma is Pointing</td>
</tr>
<tr>
<td>Session 7</td>
<td>Learning Card 4</td>
<td>Emma is Pointing</td>
</tr>
<tr>
<td>Session 8</td>
<td>Learning Card 5</td>
<td>Emma Wants to Look Too</td>
</tr>
<tr>
<td>Session 9</td>
<td>Learning Card 5</td>
<td>Emma Wants to Look Too</td>
</tr>
<tr>
<td>Session 10</td>
<td>Learning Card 5</td>
<td>Emma Wants to Look Too</td>
</tr>
<tr>
<td>Session 11</td>
<td>Learning Card 6</td>
<td>Get Emma’s Attention</td>
</tr>
<tr>
<td>Session 12</td>
<td>Learning Card 6</td>
<td>Get Emma’s Attention</td>
</tr>
<tr>
<td>Session 13</td>
<td>Learning Card 6</td>
<td>Get Emma’s Attention</td>
</tr>
<tr>
<td>Session 14</td>
<td>Learning Card 1 plus one Learning Card of the participant’s choice</td>
<td></td>
</tr>
</tbody>
</table>

In general, monitors were encouraged to have participants progress through Learning Cards in a sequential manner, from Learning Card 1 to Learning Card 6, but they were given the flexibility
to adapt the Learning Card sequence as deemed appropriate for individual participants’ needs. For example, if a participant seemed to get more frustrated with the demands of a given Learning Card, the monitor could return to an earlier Learning Card for the next episode.

After each session, participants completed a SurveyMonkey questionnaire, the “Post-Session Check”, with written and visual components that inquired about level of alertness, eye discomfort, clarity of vision, headache, stomach ache, balance, and enjoyment of having used Floreo (Attachment 5). The monitor also completed a SurveyMonkey questionnaire asking about participant tolerance of the HMD, perceived enjoyment of the VR session, any indication of negative side effects, and perceived value of Floreo VR sessions for the participant (Attachment 6).

In addition, a short, simple hand-eye coordination activity was offered to participants after the VR session, to support reorientation of their eyes to the real world. Participants then returned to their regularly scheduled day camp activities.

Results

Characteristics of the twelve participants in this pilot study are listed in Table 2. All subjects were able to follow simple verbal directions.

Table 2: Characteristics of Pilot Study Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean, range, n, or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean and range</td>
<td>13.5 (9-16)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (83%)</td>
</tr>
<tr>
<td>Female</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Caregiver-rated verbal skills</td>
<td></td>
</tr>
<tr>
<td>Verbal</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>Minimally verbal</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>Pre- or nonverbal</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>Alternative augmentative communication used</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td><strong>Medication use</strong></td>
<td>9 (75%)</td>
</tr>
<tr>
<td><strong>Corrective Lenses</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6 (50%)</td>
</tr>
<tr>
<td>No</td>
<td>6 (50%)</td>
</tr>
<tr>
<td><strong>EEG performed in the past</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7 (58%)</td>
</tr>
<tr>
<td>No</td>
<td>5 (42%)</td>
</tr>
</tbody>
</table>

Table 3: Forms of augmentative and alternative communication (AAC) used

<table>
<thead>
<tr>
<th>Communication Approach</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictures/symbols</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>Communication book/board</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Electronic communication</td>
<td>7 (58%)</td>
</tr>
<tr>
<td>AAC app</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Keyboard/Letterboard</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>American Sign Language</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>Picture Exchange Communication System</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>Facilitated Communication</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>Rapid prompting</td>
<td>3 (25%)</td>
</tr>
</tbody>
</table>
Of note, for two of the participants, baseline responses indicated that the participant regularly took prescribed or over-the-counter medication and that they participant would be on the same medication schedule over the summer, but details were not provided on the specific medications taken.

Overall, fourteen Floreo VR Joint Attention Module training sessions were conducted over a five week period. Participants attended 80% of sessions. Participants were able to complete 98% of VR sessions attended. Incomplete sessions only occurred on the first day of the pilot, and afterwards CTC staff introduced acclimating strategies that helped ease participants into the VR sessions, so all participants were able to complete sessions for the remainder of the study.

In regard to monitor survey data, a number of surveys were not completed due to participant absences during the pilot study period. One participant lost his glasses after the first five sessions, and, after a discussion between the CTC and Floreo teams after two sessions of variable participation, he was not permitted to continue using Floreo VR for the final seven sessions. In total, between participant absences and missing monitor surveys, the Floreo team received 80% of the total possible number of surveys (134 sessions with completed monitor surveys compared to 168 total sessions conducted).

In summarizing monitor survey responses, several questions were left incomplete on post-session monitor surveys, affecting totals for the four key safety and usability questions.

The results from monitor survey responses are listed in Table 4. Results indicated that 95% of the time participants tolerated HMD use. Participants were rated by monitors as seeming to enjoy Floreo VR 95% of the time. Negative side effects were described 9% of the time. Ill effects that were described in open comments included participants bothered by the headset on eight occasions, restlessness on seven occasions, eye rubbing on two occasions, and fatigue on one occasion. Of note, one participant experienced four of the episodes of restlessness and another participant experienced two of the other restlessness episodes. In addition, one participant experienced four of the “bothered by headset” episodes, and another participant experienced two of the other “bothered by headset” episodes. Monitors rated Floreo VR sessions as valuable for participants 96% of the time.

Table 4: Monitor Survey Responses

<table>
<thead>
<tr>
<th>Post-session Monitor Survey Question</th>
<th>Number with Yes Response/Total Number of Surveys Received (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the Participant tolerate wearing the headset today?</td>
<td>126/132 (95%)</td>
</tr>
</tbody>
</table>
In your opinion, did the Participant enjoy their VR session? 126/132 (95%)

Did you notice any signs of negative side effects? 12/129 (9%)

So far, do you think the Floreo sessions have been valuable to the Participant? 128/134 (96%)

No participants left the study early due to either intolerance of the HMD or VR environment, or secondary to side effects.

Participants completed the pre-session surveys at a 100% rate, and the post-session surveys showed a 98% completion rate. However, upon review and comparison with monitor survey responses, participant responses were determined to be inconsistent and the use of facilitated communication to complete the checks led the team to question the validity of the responses.

Joint Attention Measure:
Each participant's pre- and post-intervention joint attention measures were recorded. Video recordings for individual participants were later reviewed and coded in order to document the number of occurrences of specific joint attention behaviors. These behaviors included: Looks at Activity/Object; Shift Eye Gaze; Initiate Requests; Respond to Requests; Participant Initiates Interaction; Participant Responds to Interaction; Direct Eye Contact (Participant Initiated); Follows a Point; and Points.

Analysis of the pre- and post-intervention joint attention measure results showed that ten out of the 12 participants demonstrated improvement in one or more key areas (total number of interactions, initiating interactions, and eye contact). Nine out of the 12 participants had an increased number of total interactions, seven participants showed an increase in eye contact during interactions, and five participants showed an increase in instances of initiation of interactions.

Discussion
In this study, Floreo collaborated with the special education school Celebrate the Children to collect pilot data suggesting that Floreo’s mobile VR platform is both safe and feasible for children with ASD to use for the purpose of training joint attention skills. In addition, the pilot data obtained on a novel joint attention measure designed for use in school-aged children with ASD suggests that training with Floreo’s Joint Attention Module was related to improvements in social reciprocity skills in these children.
On the first day of the pilot, several participants had difficulty completing the session. As a result, CTC staff implemented acclimating strategies to help ease participants into the VR sessions, and all participants were subsequently able to complete the remainder of attended sessions. No participants dropped out of the study due to inability to tolerate use of the VR headset or participation in VR training sessions. One participant lost his glasses, and study staff determined that he should not continue in further sessions due to concern that the participant might be at greater risk for eye discomfort and headache without his corrective lenses. Side effects were noted in less than ten percent of sessions. Two participants in particular had a higher incidence of side effects that included restlessness and appearing to be bothered by the headset.

In surveys completed after working with participants, monitors at CTC provided very reassuring on the feasibility of using Floreo’s Joint Attention Module. In a high percentage of sessions, monitors rated that participants were able to tolerate the VR headset, seemed to enjoy using Floreo VR, and that the VR experience was valuable for participants. Qualitatively, monitors described progress in participants’ ability to utilize the app and increased comfort with the intervention equipment as the study progressed. Monitor comments included describing Floreo as having “a real potential to help our kids on the spectrum” and “definitely something that the kids need.”

Another objective of this study was to evaluate the feasibility of using a novel joint attention measure to rapidly assess the status of participants’ joint attention skills before and after the VR intervention was conducted. As noted above, there are no widely-used measures available for focused assessment of joint attention skills in school-age children. Because improvement in this particular set of skills is the ultimate goal of using the Joint Attention Module in children with ASD, the study team wanted to begin an exploration of the effectiveness of the intervention in the target population. Review of the video recorded pre-intervention and post-intervention joint attention measures suggested that fourteen sessions of VR-based joint attention skill training over five weeks was related to a higher total number of social interactions, more eye contact during interactions, and more episodes of initiation of interactions on the part of participants.

Several limitations should be recognized in this pilot study. One, while the protocol for the study was developed by Floreo team members with professional experience in computer science research, speech language pathology, and neurodevelopmental pediatrics, the study was carried out without the involvement of an academic research partner. Second, because the use of innovative technology for a joint attention intervention was considered a component of the standard educational approach at Celebrate the Children, no Institutional Review Board approval was sought for ethics oversight. Instead, the study protocol was reviewed by an external special education consultant, with feedback incorporated into revisions in the protocol. Third, the study team did not recruit a control group as a comparison of Floreo’s VR Joint Attention Module with treatment as usual at the school’s summer camp or with same-age peers receiving no specific social skills treatment. Finally, although the study team attempted to elicit direct feedback from participants after each session, questionnaire responses were not
consistent with what was noted by monitors or other observers. In addition, many participants’ limited communication skills impacted their ability to independently complete the surveys.

These limitations will be directly addressed in ongoing research. The study team is partnering with the Children’s Hospital of Philadelphia’s Center for Autism Research on a small business technology transfer research proposal to study safety, feasibility, and effectiveness of Floreo VR’s platform in social engagement training. The research proposal will involve ethics approval of human subjects research, and study design will incorporate control groups, likely consisting of standard treatment, wait-list groups, or both groups for comparison to VR intervention. In addition, the study team will need to consider better approaches to ensuring independence and validity of usability responses in participants with limited communication skills or mild to moderate intellectual disability in future research study design.

Overall, the results from this pilot are extremely promising for the potential of Floreo to be well-received and used by individuals with autism and the therapists, teachers, and parents working with them. This introduces a new and innovative mechanism for providing training in social communication skills in individuals with autism spectrum disorders. The long-term vision is for the Floreo VR platform to be used to develop a diverse set of lessons designed to teach a variety of skills in individuals with autism and other developmental disabilities.

References:


Attachments:
Attachment 1:
Screening Questionnaire
https://drive.google.com/open?id=1PnNtsWCXu2AMzO5As-a0GnfrP19gHnVX

Attachment 2:
Comic Book
https://drive.google.com/open?id=0B0coCwJo4GCSm96bzM2cWpWUFU

Attachment 3:
Joint Attention Measure
https://drive.google.com/open?id=1smi45LBQDXKwcoHi4HjCtfkv1PT6KdmdKB6JC2ur0

Attachment 4:
Pre-session participant survey
https://drive.google.com/open?id=0B0coCwJo4GCRVMT3J5aVZBVmM

Attachment 5:
Post-session participant survey
https://drive.google.com/open?id=0B0coCwJo4GC0UJTBw9Obng2aWc

Attachment 6:
Post-session monitor survey
https://drive.google.com/open?id=1i-VmG5LA7dDnfrdAllZgLNE0cmuDM9_y