

A Novel Feed-Forward Modeling System Leads to Sustained Improvements in Attention and Academic Performance

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Abstract

Objective: This study tested a novel feed-forward modeling (FFM) system as a nonpharmacological intervention for the treatment of ADHD children and the training of cognitive skills that improve academic performance. **Method:** This study implemented a randomized, controlled, parallel design comparing this FFM with a nonpharmacological community care intervention. Improvements were measured on parent- and clinician-rated scales of ADHD symptomatology and on academic performance tests completed by the participant. Participants were followed for 3 months after training. **Results:** Participants in the FFM training group showed significant improvements in ADHD symptomatology and academic performance, while the control group did not. Improvements from FFM were sustained 3 months later. **Conclusion:** The FFM appeared to be an effective intervention for the treatment of ADHD and improving academic performance. This FFM training intervention shows promise as a first-line treatment for ADHD while improving academic performance. (*J. of Att. Dis.* XXXX; XX(X) XX-XX)

Keywords

ADD/ADHD, academic performance, attention training, computer attention training, focused attention

ADHD is one of the most common childhood disorders, with the Centers for Disease Control and Prevention (CDC) estimating that 11% of children between the ages of 3 and 17 struggle with the disorder (Attention-Deficit/Hyperactivity Disorder Data and Statistics, 2014). The underlying mechanisms and associated cognitive dysfunctions remain unclear, with several competing theories that all point to the complexity of this disorder. Children who suffer from ADHD experience problems such as lower levels of academic achievement, higher dropout rates, higher likelihood of drug abuse, diminished social relationships, and a higher rate of mental illness than nonclinical children of the same age (American Psychiatric Association [APA], 2013; Matthys, Cuperus, & Van Engeland, 1999; McBurnett et al., 1999; Wehmeier, Schacht, & Barkley, 2010). To date, the most efficacious and best studied intervention for the treatment of ADHD remains stimulant medication (Bourgeois, Kim, & Mandi, 2014; Yang, Chung, Chen, & Chen, 2004). Although both stimulant and nonstimulant medications have been reliably shown to reduce, in the short-term, the requisite symptoms of this disorder in both children and adults, there is no clear evidence that medications effectively reduce the cognitive deficits associated with ADHD and therefore do not improve academic performance or social skills (Bidwell, McClernon, & Kollins, 2011). As to academic performance of ADHD children, evidence does suggest that optimal

dosing of stimulants can improve certain performance skills associated with sustaining attention and reaction time, but does not improve and can sometimes even impair executive functions (Bidwell et al., 2011). For example, following a stimulant intervention, reaction times may be significantly reduced, but performance on tasks requiring increased attentional or executive demands may not be consistently improved. Stimulants may actually impair performance on those executive attention tasks that require set shifting, flexibility, and planning. Moreover, the improved academic achievement scores demonstrated with stimulant interventions have not transferred to actual academic performance or increased academic achievement in children with ADHD enough to bring them into the same ranges as children without ADHD (Bidwell et al., 2011). What improvements are seen are not maintained and do not ultimately set the user on a better track for success (Molina et al., 2009).

Given the demonstrated limits of medication interventions to enhance sustained cognition and subsequently improve ADHD impairments, there has been a great deal of interest in

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nonpharmaceutical interventions that can achieve comparable effects in reducing symptomatology while demonstrating improved academic performance and sustained durability in a manner that minimizes any side effects or risks of stigma and abuse. Traditional behavioral interventions, such as parent coaching and behavioral therapy, have been shown to have little effect on the core symptoms of ADHD, although such interventions can help to manage some common comorbidities, such as anxiety and depression (Molina et al., 2009).

Neurofeedback, also known as electroencephalography (EEG) biofeedback, provides a game-like feedback for a user to regulate brainwaves and has been used as an intervention with some success for several years. Neurofeedback is based on the principles of operant conditioning, in which the participant learns to discriminate or change behavior based on rewards or punishments because of a past action (i.e., feedback). This is a slow, deliberate, and expensive process requiring many training sessions with a professional—most courses of neurofeedback tend to require 40 or more sessions, each ranging from 20 min to 1 hr or more (Kerson & The Collaborative Neurofeedback Group, 2013). The neurofeedback intervention training typically focuses on normalizing different traits of the broad EEG signal, including the theta/beta ratio. Levels of EEG brainwaves in some children with ADHD exhibit clear differences when compared to the brain signals recorded from people without ADHD, including reduced levels of activity in the high-frequency bands (beta waves), and an increase in lower frequency bands, especially theta waves from 4 to 7.5 Hz (Loo & Barkley, 2005). Currently, the literature is divided about neurofeedback's effectiveness as an intervention for the treatment of ADHD. Two recent meta-analyses came to conflicting conclusions with one supporting its use as an efficacious and specific (Level 5) treatment intervention for ADHD (Arns, de Ridder, Strehl, Breteler, & Coenen, 2009) and the other indicating that more randomized, controlled clinical trials are warranted (Lofthouse, Arnold, Hersch, Hurt, & DeBeus, 2012). Although randomized, controlled studies have shown positive results, more recent, properly blinded studies have not shown the same strong results (Holtmann, Sonuga-Barke, Cortese, & Brandeis, 2014). One significant limitation of neurofeedback is that the training relies upon matching EEG signals to a "normal" population template. Although a participant's conscious attempt to regulate their brain activity may strengthen the neural circuits of the brain that are most affected by ADHD and change the traits seen in the EEG signal to appear more normal, it is difficult for a participant with ADHD to repeatedly manage their brain activity over many training sessions. Moreover, the neurofeedback intervention does not isolate and target specific cognitive skills, such as elements of attention or impulse inhibition.

Another treatment intervention, cognitive training, involves performing selected challenge tasks on a computer

or mobile device that are designed to train and strengthen specific cognitive abilities, such as selective attention, inhibition control, or working memory (Bidwell et al., 2011; Klingberg et al., 2005; Klingberg, Forssberg, & Westerberg, 2002). The cognitive training approach includes nongame training regimens (e.g., Cogmed®), brain training games (e.g., Nintendo®'s Big Brain Academy), and commercial action video games (e.g., Call of Duty® series). These techniques have shown some degree of improvement in different populations (Dye & Bavelier, 2010; Feng, Spence, & Pratt, 2007; Kawashima et al., 2005; Olesen, Westerberg, & Klingberg, 2004; Westerberg et al., 2007). Although this approach initially appeared to be a viable treatment for ADHD, as research accumulates, studies with more strictly designed controls and meta-analyses have cast doubt on the effectiveness of cognitive training as a possible effective treatment for ADHD (Rapport, Orban, Kofler, & Friedman, 2013; Sonuga-Barke et al., 2013; Thompson et al., 2013). Given the vast number of differences between different cognitive training techniques, from the skills trained to the format in which the training is presented, it is difficult to point to any one reason that cognitive training does not consistently lead to improvements for children with ADHD. Some possibilities may include lack of engagement for the user, ineffectively training the cognitive skills or focusing on the wrong cognitive skills to train, insufficient challenge levels, or failure of the participant to transfer the newly trained skills beyond the cognitive skill training. The lack of efficacy is certainly also due, at least in part, to the current limited understanding of the relationship between ADHD and its component cognitive skills. Given the complexity of that relationship, it appears advisable to not focus training on only one skill, but rather train a set of skills that children with ADHD struggle to use effectively (Castellanos, Sonuga-Barke, Milham, & Tannock, 2006; Epstein et al., 2003; Jonsdottir, Bouma, Sergeant, & Scherder, 2006; Rapport et al., 2013).

The lack of clear success in either neurofeedback or cognitive training interventions has motivated the development of a novel learning methodology presented here that has not been used solely as an intervention in the treatment of ADHD, but more generally to support the cognitive skill development underlying attention and impulse inhibition control in children. When this key learning methodology has been implemented to teach cognitive skills, users have experienced the greatest levels of improvement (Dowrick, 2012a, 2012b; Dunn, Gillig, Ponsor, Weil, & Utz, 1986). This critical learning methodology is referred to as feedforward modeling (FFM), a method of learning that illustrates a desired future behavior or path to a goal. FFM moves the focus of training to be about how one could act correctly in the future, in contrast to its opposite, feedback, which focuses on what one has done in the past to provide reflection and the basis for adjusting behavior on the next

occurrence. The essence of FFM teaches a participant to restructure behaviors and actions they already possess in that moment into what appears to be a new skill or combination of behaviors to achieve a goal. FFM methods have been used by a small number of researchers and therapists for decades and have been shown to lead to impressive, rapid learning of new behaviors (Dowrick, 1999, 2012a, 2012b; Dowrick, Kim-Rupnow, & Power, 2006). The best known applications of this learning methodology have incorporated key capabilities from video technology. Video-based FFM involves eliciting the desired behaviors from a participant, filming these behaviors, and then editing the video to show the participant using these behaviors in a situation where the participant had previously been unable to use the desired behaviors. Using video-based FFM has led to dramatic improvements, sometimes only requiring one training session to teach the desired behaviors. In addition, the research has shown that newly modeled behavior improvements have been sustained as participants rapidly learn from the positive experience in achieving the future goal presented in front of them (Dowrick, 2012b).

Interestingly, there is evidence that FFM can lead to greater success if aptly applied within interventions like neurofeedback and cognitive training. Despite neurofeedback's history as an operant conditioning training regimen, there is evidence in the literature that participants who have the greatest success using forms of biofeedback do not use operant conditioning principles, but rather adopt a FFM strategy (Dunn et al., 1986; Utz, 1994). In contrast to the operant conditioning feedback methodology, where the participant develops a new skill based on trial and error as they learn to distinguish signals based on the feedback they receive, the FFM approach involves the participant using preexisting skills in a novel way where the goal achievement merely serves as information about whether the skills they are trying to use are successful (Basso & Belardinelli, 2006; Utz, 1994).

There is evidence that success in cognitive training may also require a FFM strategy, even though that strategy is not explicitly trained or required. Much like in biofeedback, a user can implement a reactive play style where they respond to feedback in the moment; however, when they use this strategy, they are unlikely to experience much benefit from the training. A user of an FFM strategy plays more proactively by adjusting their action in advance of the next trial or challenge (Cardoso-Leite & Bavelier, 2014). Cardoso-Leite and Bavelier (2014) believe that the proactive FFM approach is necessary to achieve the improvements seen in cognitive training, especially with the improvements observed as a result of playing action video games.

The FFM training system presented here as a possible intervention for both the treatment of ADHD and training of underlying cognitive skills draws some inspiration from the limits of both cognitive training and neurofeedback. This

novel FFM technology adds an intentional, proactive feed-forward component to the training. One critical way this is implemented is by providing a player's own states of attention, as managed by a unique calibration and use of a player's attention-based EEG signals. By using a player's own state of attention from moment to moment, the player must engage proactively to succeed and quickly learns that attention is required to optimize a learning environment. This sets the stage for the development of the multiple cognitive skills comprising attention and impulse control. This FFM of one's instant states of attention scaled 0% (lowest level of attention) to 100% (maximum level) in the virtual world of an adventure story enables the player to recognize and manage their actual levels of attention and learn to control their attention to maximize performance in the game and therefore skill development. That is, the player can directly experience the consequences of attentional control—the higher and longer the player is able to maintain their attention levels, the more success they will have because the learning environment for the development of multiple cognitive skills will be closer to ideal. This is an important distinction that allows the player to recognize the moment of distraction or impulsivity and its consequence, and use this knowledge to avoid distraction and succeed against multiple challenge tasks that underlie developing each cognitive skill. Through game engagement and inherent desires to succeed in the game, participants are consequently motivated to continue to practice controlling their inattention and impulsivity as it affects their performance in the video game (Dowrick, 2012b).

The FFM technology method is dependent on the capture, conversion, and calibration of discrete EEG factors of each individual player's primary neural circuits of attention. The FFM technology is then able to convert these factors into attention state levels. The resulting personalized "cognitive signature" enables direct, personalized communication to a customized curriculum for training cognitive skills through an EEG feed-forward brain-to-computer interface (BCI). The player uses their attention state to move their avatar through the game, providing a proactive use of their attention to achieve future behavior or path to a goal. To continue to have success in each moment of the game, it does not matter how attentive the player was before, as it would in neurofeedback, but on how attentive they are now to move forward as fast as possible while faced with challenging tasks in the path. In this manner, the player uses FFM because they are able to harness an underutilized skill they already have—to pay attention—and apply and develop it to achieve a new goal of succeeding in gameplay (Basso & Belardinelli, 2006; Dowrick, 2012b). As the player learns how to increasingly use their attention levels to move the game avatar, each video game session dynamically challenges the player within a curriculum of cognitive skill development tasks that first teach and

develop the skill and another series of tasks designed to effectively retain the newly developed targeted skill. An adaptive model of difficulty levels presents challenges that are just above but in reach of a player's actual performance. As the player's performance varies throughout gameplay, the adaptive skill model proportionately moves to an appropriate challenge level that leads a player to see a modeled level of performance that is challenging but not too difficult that they will not be able to succeed. This adaptive challenge level encourages the player to remain engaged and to continue progressing toward ever higher levels of cognitive skill performance.

This FFM training system is designed to directly optimize the cognitive skills underlying attention and impulse control and to be as or more effective, long-lasting, and safer than medications or any other currently available interventions for the treatment of ADHD in children and adults. Using game applications of the FFM system to train 2 to 4 times per week in a clinic for a total of 20 to 24 sessions has already resulted in initial success in reducing inattentive and impulsivity symptoms in children with ADHD as assessed by parents, teachers, and clinicians (Lim et al., 2010; Lim et al., 2012). The current study seeks to further this evidence by using a randomized, controlled, parallel-group design and measuring objective tests of academic achievement and performance in addition to parent- and clinician-reported scales of ADHD symptomatology. We hypothesize that, as seen in previous studies, training for 24 sessions over 6 to 8 weeks will lead to greater improvement than the control group undergoing nonpharmacological interventions in a community care setting.

Method

This protocol was approved by Chesapeake IRB, an independent, accredited institutional review board. Chesapeake IRB operates in compliance with Food and Drug Administration (FDA) regulations as described in 21 Code of Federal Regulations (CFR) Parts 50 and 56, Department of Health and Human Services (DHHS) regulations as described in 45 CFR 46, guidelines resulting from the International Conference on Harmonization (ICH), Good Clinical Practice (GCP), and the Common Rule.

Participants

Recruitment. The study took place at three clinical sites, one in New York and two in Massachusetts. Each site was overseen by one training coordinator (TC) and one clinician/investigator. Participants were recruited via clinician recommendations as well as print and web-based advertisements. Interested candidates scheduled initial consultations with one of the study clinicians to determine eligibility and assess the severity of ADHD symptoms.

Inclusion criteria. To participate in the study, participants needed to be children between the ages of 8 and 12, receive an official ADHD diagnosis according to *Diagnostic and Statistical Manual of Mental Disorders (DSM)* criteria by one of the study clinicians, and score a 14 or more on the Inattention subscale of the clinician-rated ADHD-Rating Scale (ADHD-RS), indicating mild-to-moderate inattentive symptoms (DuPaul, Power, Anastopoulos, & Reid, 1998; Wigal & Wigal, 2006). Study clinicians confirmed an ADHD diagnosis according to *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; *DSM-IV*; APA, 1994) criteria with all participants and also completed a clinician-rated ADHD-RS.

Exclusion criteria. Noneligible children were those on medication for ADHD or comorbid psychiatric conditions, and those who had sensorineural deficits (blindness or deafness) or known developmental delays as defined as an IQ of 70 or below. Children with a medical history of epileptic seizures, traumatic brain injury, stroke, central nervous system tumor or lesion, cerebral hypoxia, skull fracture, or encephalitis were also excluded from the study.

Enrollment. Forty-seven children consented to participate in the current study. Forty-six children were randomized because one participant was falsely deemed eligible during the clinician evaluation and then excluded prior to randomization (32 male, 14 female, $M = 9.57$, $SD = 1.34$). Figure 1 provides an overview of enrollment and dropouts throughout the course of the study. All participants lived in the Greater Boston Area or one of the New York City Boroughs at the time of the study. Dropouts occurred due to scheduling conflicts or no longer meeting the inclusion criteria (i.e., beginning a medication treatment regimen for a comorbidity).

Procedures

During an initial consultation, the clinician evaluated the participant's inattentive symptoms using an ADHD-RS and overall inattentive severity using a Clinical Global Impression–Severity (CGI-S) scale (see “Behavioral Measures” section) to ensure eligibility. At this time, clinicians also spoke with interested parents about all of the non-pharmaceutical options available to improve their children's behavior and attention levels. They reviewed the study and obtained written informed consent from the parent and written assent from the child.

After the clinician consultation, participants completed a baseline assessment visit where the participating child completed tests of academic achievement and performance while the parent filled out the ADHD-RS Home Version about their child's behavior. At two of the three sites, participants were also assessed using the Quotient® ADHD

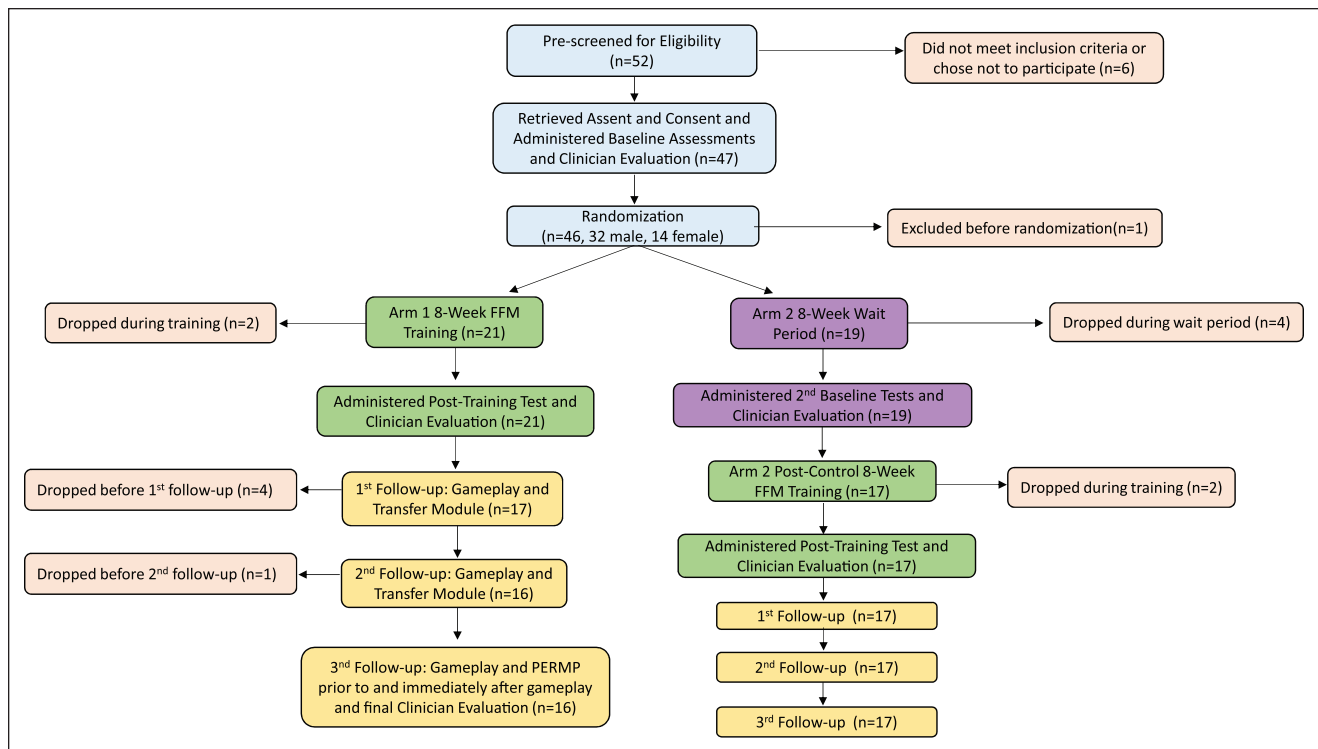


Figure 1. Flow of participants through the study.

Note. PERMP = Permanent Product Measure of Performance.

System (see “Behavioral Measures” section). At the end of this session, participants were randomly assigned to one of two groups. Randomization was stratified by site so that there were approximately equal numbers of participants in Group 1 and Group 2 at each site. Group 1 immediately received the 8-week training using the FFM system application, while Group 2 acted as the control group and for 8 weeks received nonpharmaceutical care typically offered to patients. These standard nonpharmacological intervention options included cognitive behavioral therapy once a week, therapeutic tutoring once a week, 3 to 4 parent coaching sessions, or minimal or no structured intervention with periodic clinician visits to monitor symptoms. After the first 8 weeks were completed, Group 2 met with the clinician to reassess symptoms and completed another baseline assessment. After these visits were completed, the control group participants received the FFM training for 8 weeks. This allowed for confirmation that both groups would see the same amount of improvement with FFM training and also served as an incentive for the control group.

Once the active group’s training with FFM system was completed (Week 8 for Group 1 and Week 16 for Group 2), participants completed clinician visits and assessment sessions using the same assessments as baseline. Group 2 did not complete the Woodcock–Johnson Assessment at Week 16 as there were only two versions, which were used for prior assessments. Participants returned for three monthly

booster sessions that involved one gameplay session, including a skills transfer module. At the third monthly follow-up, in lieu of the skills transfer module, the participant completed the Permanent Product Measure of Performance (PERMP) before and after the gameplay. The booster sessions were used to evaluate whether participants remembered how to use the game after no longer playing on a regular basis. Parents were also asked to complete the ADHD-RS. At the end of the 3 months of follow-up, participants had a final clinician visit to assess their symptom severity.

Behavioral Measures

ADHD-RS. The ADHD-RS is an 18-item scale that assesses symptom severity associated with ADHD. The clinician completes it based on their interactions and observations of the participant and discussion with parents. Parents were also asked to complete the Home Version of the ADHD-RS, which has been validated for independent completion by parents (DuPaul et al., 1998). The ADHD-RS is comprised of an Inattention subscale and a Hyperactivity/Impulsivity subscale, as well as a Combined score that is calculated as the sum of the two subscale scores. Each of the 18 items are rated on a 4-point scale (0 = *never/rarely*, 1 = *sometimes*, 2 = *often*, 3 = *very often*) and correspond to the diagnostic criteria found in the *DSM-IV* (Goodman,

Faraone, Adler, & Dirks, 2010; McDonagh, Peterson, Thakurta, & Low, 2011; Wigal, Kollins, Childress, & Squires, 2009; Wigal & Wigal, 2006).

CGI scale. The CGI is comprised of two companion one-item measures that assess the severity of functioning and psychopathology before and after initiation of an intervention. The clinician considers his or her knowledge of the patient's medical history, behavior, psychosocial circumstances, symptom severity, and the impact that these symptoms have had on his or her ability to function to score the participant (Guy, 2000). On the CGI-S, participants were rated on a 7-point scale (1 = *normal, not at all ill*; 2 = *borderline mentally ill*; 3 = *mildly ill*; 4 = *moderately ill*; 5 = *markedly ill*; 6 = *severely ill*; 7 = *extremely ill*). The Clinical Global Impression-Improvement (CGI-I) scale assesses how much the participant had improved or worsened since the initial visit. The CGI-I scale was also rated on a 7-point scale: 1 = *very much improved*, 2 = *much improved*, 3 = *minimally improved*, 4 = *no change*, 5 = *minimally worse*, 6 = *much worse*, or 7 = *very much worse* (Goodman et al., 2010; McDonagh et al., 2011; Wigal et al., 2009).

Quotient®ADHD system. Using a motion tracking system, a forehead reflector, a liquid crystal display (LCD) screen showing visual stimuli, and a keyboard used to respond to stimuli, the Quotient® (Pearson Education, Inc., Westford, MA) is a diagnostic tool cleared for marketing by the FDA to provide objective measures of the symptoms of ADHD to aid a clinician in diagnosis (Sumner, 2010). The Quotient® measures attention by requiring the participant to perform a task where he or she is instructed to hit the space bar when the target (8-point star) appears on the screen and to withhold response when the nontarget (5-point star) appears on the screen. The system creates a composite score based on the participant's levels of hyperactivity, impulsivity, and attention compared with norms based on age, grade, and gender. The Quotient® was only administered at two out of the three clinical sites due to availability of the system.

Academic Measures

Permanent Product Measure of Performance (PERMP). The PERMP math test consists of a 10-min validated math test containing 400 ability-appropriate math problems designed to measure a child's ability to stay on task and pay attention (Wigal & Wigal, 2006), which is related to their academic performance abilities. The participant is instructed to correctly answer as many problems as possible within 10 minutes, without skipping any problems. Each test is graded by counting the number of attempted and the number of correctly completed problems (McDonagh et al., 2011). The PERMP is a reliable and valid measure frequently used to evaluate response to stimulant medication (Kimko et al.,

2012; McCracken et al., 2003; Wigal et al., 2009; Wigal, Truong, & Stehli, 2012; Wigal & Wigal, 2006; Wigal et al., 2011). During the baseline session, participants took a math pretest PERMP to determine the appropriate math difficulty level. Participants were given tests based on the difficulty level established at pretest each time they took PERMP tests. During each administration of the academic measures, the PERMP was given 2 times: once before playing the game (Test 1) and once after playing the game (Test 2). During the baseline assessment for Group 2, in lieu of playing the game, there was a 30-min break between Test 1 and Test 2. Different sets of problems were administered throughout the study to minimize practice effects.

Woodcock-Johnson Third Edition (WJ-III). The WJ-III Tests of Achievement includes a set of tests that assess achievement in reading and mathematics, written and oral language ability, and curricular knowledge (DuPaul et al., 2006). Subtests can be administered to individuals or groups, and are normed to age and grade level. Three subtests were used in the current study (Reading Fluency, Math Fluency, and Understanding Directions) because they were closely related to attention abilities (DuPaul et al., 2006; McClelland et al., 2007; Vile Junod, DuPaul, Jitendra, Volpe, & Cleary, 2006). Form A of the WJ-III was administered at the baseline session and Form B of the WJ-III was administered at the completion of training for Group 1 or the end of the nonpharmacological intervention for Group 2 to avoid administering the same test twice. No additional forms were available to evaluate maintenance of effects or the effect of training for Group 2.

Training

Gameplay. The FFM training system included the game (Cogoland©) on a PC laptop and an EEG headband with three frontal sensors (Zeo Sleep Manager™, Zeo, Inc., Boston, MA). The training consisted of a calibration exercise, 24 game sessions, and 10 skill transfer module sessions. The sessions lasted up to 30 min and were supervised by the TC to ensure completion.

During the initial calibration, the software created a discriminate EEG model based on the participant's performance on computerized exercises intended to provoke states of attention and inattention. The EEG recording during the calibration was used in a scoring algorithm that produced an index related to the participant's state of attention in near real time.

During each game session, participants played a 3D computerized graphic cognitive training game called Cogoland©. As the participants played the game, their EEG waves were recorded simultaneously via the EEG sensors embedded in the headband. The EEG waves were used to quantify a participant's level of attention in real time, which ultimately controlled the speed of the character in the game. Game sessions typically lasted between 15 and 20 min.

The game consisted of three attention and inhibition skill development levels as the FFM challenged the participant to move the avatar character quickly around a track while ignoring auditory and visual distractors. The second and third levels added tasks where the participants were required to jump for the correct target fruit and not jump for nontargeted fruit. Participants were rewarded with points for their correct jumps and nonjumps while points were deducted for incorrect commissions and omissions.

Transfer modules were played by each participant to increase skill retention for transfer to real-life applications. This skills transfer exercise contained multiple-choice questions that were matched to the participant's academic grade level so the newly learned attention and impulse inhibition skills would be exercised to optimize retention.

FFM training schedule. The first training session consisted of a 15 to 20 min calibration exercise followed by one round of Level 1 gameplay. During the second training session, the participants were asked to complete PERMP assessments before and after the training session. Participants continued to train 3 to 4 times per week for 6 to 8 weeks. On the even-numbered sessions (fourth visit, sixth visit, etc.), the skills transfer module was administered to the participants. During the 12th and 24th sessions, a pregame and postgame PERMP was administered instead of the skills transfer module. As the FFM training progressed, game skills development was increased. Participants moved to the second skill level set during Session 5 and to the third skill level set during Session 14.

Results

To establish the effects of FFM training versus the control group, all measures were analyzed using a 2 (group) \times 2 (test) \times 3 (site) repeated-measures ANOVA. There was no effect of site except for the Quotient®, so site was dropped from the repeated-measures ANOVAs for all other measures. Missing data were handled per protocol, so participants with missing data were not included for that analysis. Participants who dropped out before the end of the initial FFM intervention period were not included in the analyses. Those who dropped out during follow-up were still included in this primary analysis but were not included in analyses of maintenance effects. To characterize the effect and sustainability of the FFM training intervention, the pooled training data from both groups were entered into a 2 (group) \times 3 (test: prestudy, posttraining, follow-up for Group 1; postwait, posttraining, follow-up for Group 2) repeated-measures ANOVA intervention analysis and any significant interactions were analyzed using post hoc *t* tests.

Behavioral Measures

ADHD-RS. The post-study clinician ADHD-RS evaluation was not available for one participant in Group 1, so that

participant was excluded from the analysis. The combined score on the ADHD-RS showed significant effects of group, $F(1, 37) = 17.668, p < .001, \eta^2 = .323$; test, $F(1, 37) = 25.689, p < .001, \eta^2 = .410$; and a Group \times Test interaction, $F(1, 37) = 28.428, p < .001, \eta^2 = .434$. The subscores for inattention and hyperactivity/impulsivity reflected the same pattern (see Table 1). This indicates that the control group's symptoms were slightly more severe than the FFM training group at the beginning of the study; however, this difference was smaller than the improvement seen in the FFM training group. The effect of time and interaction of group by time are indicative of a reduction of 36% in ADHD symptoms for the immediate FFM training group (Group 1).

In the intervention analysis of the pooled FFM training data, there was no effect of group, $F(1, 29) = 1.865, p = .183, \eta^2 = .060$, and no interaction, $F(1, 29) = 0.431, p = .516, \eta^2 = .015$, but there was an effect of test, $F(1, 29) = 66.151, p < .001, \eta^2 = .695$, indicating that both groups achieved the same degree of improvement with FFM training. Post hoc analyses also indicated that there was a significant difference between before FFM training and after training, as well as before FFM training and follow-up (all $ps < .001$). The improvements due to FFM training were also maintained through the 3-month follow-up, as indicated by a lack of significant differences between the two time points. This pattern also held for each of the two subscores (see Table 1).

ADHD-RS scores reported by parents closely matched those reported by clinicians with effects of group, $F(1, 38) = 13.132, p < .001, \eta^2 = .257$; time, $F(1, 38) = 14.695, p < .001, \eta^2 = .279$; and a Group \times Time interaction, $F(1, 38) = 6.237, p = .017, \eta^2 = .141$. The control group was reported as being slightly more severe than the FFM training group before the study. Group 1's symptom severity improved by 31%, and Group 2 did not show any improvements. This improvement was also observed in the inattention and hyperactivity/impulsivity subscores (Table 1). When looking at the effect of FFM training for both groups, the amount of improvement was the same for each group as demonstrated by an effect of time, but no effect of group or interaction ($ps > .2$) in the pooled intervention analysis. As was seen for the clinician ratings, the FFM improvements were still evident at the 3-month follow-up for all scores (see Figure 2). The reductions in symptoms reported on the ADHD-RS indicate that FFM training led to improvements that would be categorized as moving from moderately severe symptoms to near normal levels.

CGI. At the second clinician consultation, the severity measure of the CGI was not completed for seven participants (only improvement was noted), so they could not be included in this analysis. The ANOVA comparing training with standard nonpharmacological care reported effects of both group, $F(1, 31) = 7.110, p = .012, \eta^2 = .187$, and time,

Table 1. Mean Scores (Standard Deviation) Before and After Training for Both Groups.

Measure	Pretraining		Posttraining	
	Trained	Control	Trained	Control
ADHD-RS				
Clinician	34.5 (8.0)	37.2 (8.2)	22.2 (9.7)	37.4 (9.7)***
Parent	32.4 (11.9)	36.7 (8.2)	22.5 (14.6)	35.7 (9.3)***
CGI	4.32 (0.77)	4.42 (0.69)	3.14 (1.17)	4.32 (0.58)***
Quotient				
Inattention score	6.79 (2.10)	6.64 (2.46)	7.93 (2.03)	6.65 (2.54)
PERMP				
Test 1 correct	76.3 (41.8)	77.4 (54.7)	103.3 (56.3)	76.5 (11.7)*
Test 1 attempted	78.4 (42.2)	83.5 (55.3)	105.3 (56.9)	71.9 (56.7)*
Test 2 correct	68.6 (39.2)	59.9 (52.8)	101.4 (61.3)	68.9 (51.3)*
Test 2 attempted	69.9 (39.2)	65.5 (53.1)	103.1 (61.9)	73.5 (50.3)*
WJ-III				
Reading fluency				
Age equivalent	10.94 (2.77)	12.77 (3.35)	11.14 (3.19)	12.89 (3.52)
Grade equivalent	5.57 (2.79)	7.29 (3.18)	5.74 (3.15)	7.38 (3.25)
Math fluency				
Age equivalent	9.68 (2.41)	9.71 (2.83)	10.04 (2.79)	10.58 (4.34)
Grade equivalent	4.27 (2.38)	4.41 (0.74)	4.50 (2.81)	4.87 (3.27)
Understanding directions				
Age equivalent	10.27 (2.97)	10.76 (3.02)	11.62 (3.96)	10.88 (3.01)
Grade equivalent	5.04 (3.56)	5.64 (3.59)	6.64 (4.65)	5.81 (3.57)

Note. ADHD-RS = ADHD–Rating Scale; CGI = Clinical Global Impression; PERMP = Permanent Product Measure of Performance; WJ-III = Woodcock–Johnson Third Edition.

* $p < .05$. *** $p < .001$.

$F(1, 31) = 13.627, p = .0009, \eta^2 = .305$, and a significant interaction of the two, $F(1, 31) = 12.201, p = .001, \eta^2 = .282$ (see Table 1). The effect of group was related to the fact that the FFM training group was rated as being slightly less severe than the control group, as was seen on the ADHD-RS scores. However, this initial difference was much less than the amount of improvement seen from the FFM training group and equal to the change the control group experienced. An analysis of the pooled effect of FFM training for each group confirmed that the slight difference in severity did not change the effectiveness of the FFM training—effect of group and interaction with time $ps > .9$; effect of time: $F(1, 26) = 37.471, p < .0005, \eta^2 = .590$. The CGI indicates that FFM training led to improvements from being categorized as moderately ill to only being mildly ill.

Quotient® ADHD system. There were no significant main effects or interactions on the global measure of the Quotient® ADHD System (all $ps > .2$). For the inattention subscore, there was an effect of time, $F(1, 18) = 5.207, p = .035, \eta^2 = .224$, and a trend of a Group \times Time interaction, $F(1, 18) = 3.511, p = .077, \eta^2 = .163$, for the inattention score. Unlike the other measures, this was due to the FFM training group scores worsening, while the control group

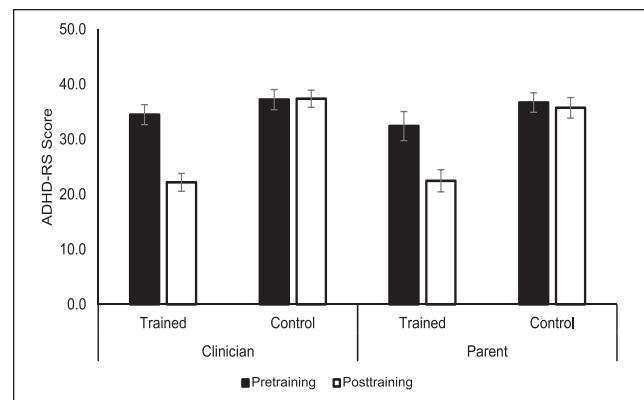


Figure 2. Mean ADHD-RS combined scores for the trained and control groups before and after the initial 8 weeks of intervention as reported by clinicians and parents. Error bars are standard error.

Note. ADHD-RS = ADHD–Rating Scale.

remained the same. On the motion measure, there was a significant effect of site, $F(1, 18) = 6.364, p = .0213, \eta^2 = .261$, where one site had a consistently higher score for motion, a trend that can also be seen in the ADHD-RS hyperactivity scores, although it was not significant in that measure.

Looking at the pooled effect of FFM training for each group, the same pattern emerges in the inattention score. There was a significant effect of time for both the inattention, $F(1, 18) = 10.718, p = .004, \eta^2 = .373$, and global, $F(1, 18) = 2.353, p = .030, \eta^2 = .236$, scores. There were no significant interactions ($ps > .3$), but as was seen in other measures, the FFM trained group was less severe in the motion score than the control group, $F(1, 18) = 5.509, p = .031, \eta^2 = .234$. The effects of time were due to worsening inattention scores after FFM training (see Table 1).

While these results were unexpected, further investigation of the literature indicated that computer-based tasks of cognitive abilities, such as the Quotient®, are not correlated with reports of behavior and clinician diagnosis (Bidwell et al., 2011; Epstein et al., 2003; Jonsdottir et al., 2006) or improvements from training (Steiner, Sheldrick, Gotthelf, & Perrin, 2011). Two Group 1 participants in particular showed extreme increases in their scores from before training to after training, one of whom returned to baseline at the 3-month follow-up evaluation. Given that our sample size is small, it is hard to say whether the FFM training group as a whole truly worsened or whether most of the changes are within natural variation and these two outliers are driving the effect. More research is necessary to explain why participants became worse, but this may provide an explanation for why the Quotient® results do not show the improvements seen on the other measures in this study.

Academic Measures

PERMP. The performance on the PERMP is listed in Table 1. For all four measures—correct and attempted both before (Test 1) and after (Test 2) gameplay—the effect of time was significant (all $ps < .02, \eta^2s > .150$) and there was a significant interaction between group and time ($ps < .01, \eta^2s > .150$), but no significant effect of group ($ps > .4$). Accuracy was generally high on this test—The majority of problems attempted were correct (>90%). The lack of effect for group indicates that both groups were able to complete the same number of problems at the beginning of the study. After the initial 8 weeks, Group 1 increased the number of problems they could complete in the time limit by 26% on average, whereas Group 2 did not show any increase in the number of problems (see Figure 3).

There was no difference in the gains between groups once FFM training was completed ($ps > .5$) and no interactions ($ps > .1$). There was the effect of time ($ps < .004, \eta^2s > .200$) showing improvement with FFM training for both groups. However, Bonferroni-adjusted post hoc t tests indicated that the statistical significance of the increase in performance was not sustained at 3 months.

WJ-III. There were only two versions of WJ-III available (Forms A and B), so the WJ-III assessment was only

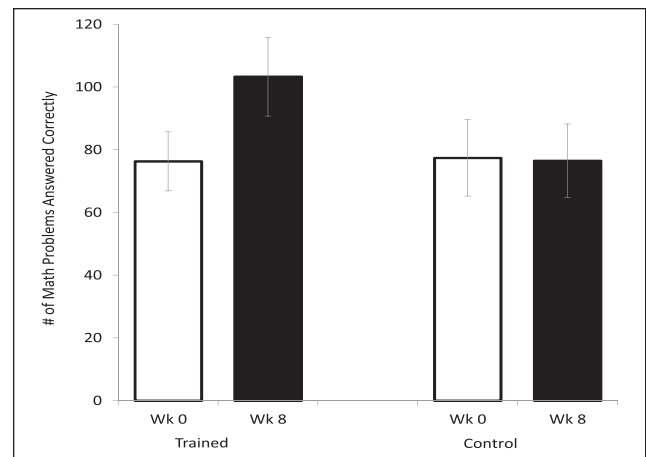


Figure 3. Mean number of questions answered correctly on the PERMP before and after the initial 8 week intervention period. Error bars are standard error.

Note. wk = week.

completed at baseline and after the first 8 weeks (FFM training for Group 1; standard nonpharmacological care for Group 2). Six participants did not complete the WJ-III because a different test was initially used and found not to be appropriate to this cohort. In addition, one participant who completed Reading and Math Fluency tests did not complete Understanding Directions. All subtests reported both age and grade equivalents, and repeated-measures ANOVAs were completed for both. For Math Fluency, there was an effect of time in age and grade level, age: $F(1, 29) = 7.037, p = .013, \eta^2 = .195$; grade: $F(1, 29) = 14.076, p < .001, \eta^2 = .327$; however, the age effect disappeared when adjusted for the 2 months that had passed between tests. There were no effects of group or interactions ($ps > .2$). Reading Fluency did not show any improvements ($ps > .1$). In Understanding Directions, there was not an effect of group ($ps > .9$). There was a trend of improvement over time and an interaction between time and group, but these were not significant and had very small effect sizes ($ps > .05, \eta^2 < .1$; see Table 1).

Discussion

After 8 weeks of either FFM training or nonpharmacological community care options, the FFM training group showed improvements in ADHD symptoms whereas the control group did not demonstrate meaningful improvement. Clinicians reported a 36% reduction in symptoms on the ADHD-RS, with similar improvement reported on the CGI. Parents also reported reduction in the symptoms after FFM training of approximately 31%. The nonpharmacological interventions did not lead to significant improvement of symptoms. The FFM training group also showed some improvement on measures of academic performance,

demonstrating a greater ability to stay on task and thereby correctly answer more questions on the PERMP after training. A trend was also observed toward improvement in the FFM training group's ability to control their impulses and follow directions on the WJ-III Understanding Directions test. The two groups did not differ on the measures of Reading Fluency and Math Fluency, which may have been due to the short time limit of these tests. Although Math Fluency and the PERMP are similar tests, we saw improvements with the 10-minute time limit of the PERMP, but not on the Math Fluency test with the 3-minute duration. All FFM training improvements were also sustained 3 months after training ended. While in some cases applying Bonferroni corrections for multiple comparisons led to improvements losing statistical significance, numerically they did not return to baseline levels.

All of the academic measures were carefully chosen to minimize retesting (practice) effects by having multiple versions of the test. The WJ-III is designed and has been validated to be used across multiple time periods using different forms of the test (Forms A and B). The PERMP is designed to be administered multiple times within 1 day and has been validated as a measure that is sensitive to medication levels throughout the day, confirming a lack of practice effects on different versions of the test. In light of this, we would not expect to see improvements merely due to having experience taking the test. Even with this effort, the data overall show slightly higher scores after retest. However, these retest improvements were very small and not statistically significant.

We did not observe FFM improvements from training on the Quotient® ADHD System. Although this finding was unexpected, a further review of the literature indicates a lack of correspondence between continuous performance tasks like the Quotient® and symptomatology in ADHD (Barkley, 1991; Epstein et al., 2003; Jonsdottir et al., 2006). This may be due to ADHD inattention being related to a general construct of "attention" and not any one particular type of attention ability (Castellanos et al., 2006; Jonsdottir et al., 2006). Other treatments for ADHD symptoms have reported a similar lack of improvement on these computer-based performance tasks. In addition to a lack of improvement overall, the FFM training group displayed a worsening of symptoms, which may be driven by two outliers in the group. Further research is necessary to understand the causes of both the discrepancy between Continuous Performance Test tasks and parent and clinician behavioral reports, and whether a larger training group would also deteriorate after training.

This randomized, controlled trial demonstrates that this FFM system is a superior option to current nonpharmacological interventions provided in community clinics to treat children with ADHD. Many of the participants in this study had not previously been on medication, and their parents

were seeking nonmedication treatment options. Although carefully controlled behavior therapies can be effective in alleviating ADHD symptoms (Jensen et al., 2001), the treatment options currently available in a more general community care setting, such as the nonpharmacological approaches used in the control group, lead to limited reductions in severity of ADHD symptomatology, especially after only 8 weeks. In contrast, this FFM training led to significant and sustained reductions in ADHD symptomatology and in selected measures of academic performance. The nonpharmacological approaches generally show better performance when they are extended over longer periods and combined with medication treatment (Bidwell et al., 2011; Jensen et al., 2001). Even without medication, this FFM training system led to significant and sustained severity reductions, so FFM training may be a viable first-line treatment option for ADHD. The potential for FFM training to enhance the effect of medication or reduce the required maintenance dose of medication is an important question for future studies.

Although implications of these results are exciting, it is also important to acknowledge the limitations of this study, which could be addressed in future studies. The group assignment was not blinded, so clinicians, parents, and participants knew whether they were in the FFM group of interest or the control group, which potentially introduces expectation bias, where clinicians and parents may (consciously or unconsciously) focus on the positive behaviors and inflate the reported effect for the FFM training group, or conversely, discount improvements for participants in the control group. To partially address this issue, the study also included objective academic measures and evaluated the durability of these improvements following completion of FFM training. The improvements observed on these measures for the FFM training group, when compared with controls, demonstrated meaningful changes in academic performance. If expectation was the primary driver of the effects seen, the objective academic measures would not be expected to improve to the degree observed in this study. If expectation was the primary driver of the effects seen, the sustained measures of improvement would also not have been maintained or improved after 3 months of follow-up.

A second limitation concerns the intervention options for the control group. The goal was to provide participants with the care that would typically be available for families who choose not to use medication. The control group in this study had the option to pick from a variety of treatments, including to not receive treatment. This design presented the limitation that we could not compare FFM training against any one evidence-based treatment. However, this design does more closely simulate the experience of typical families who have a child diagnosed with ADHD and do not want to use medication.

The fact that there was not a comparison group during the follow-up presents another limitation. Because we

wanted to verify that there would not be a difference in training response between the two groups, the control group was given training after they completed the 8-week intervention of choice. This design choice resulted in not having a control group to test maintenance effects. As a result, it is not clear how much improvement would be seen in the control group after completing the 8 weeks of their intervention of choice. However, given that there were very few practice effects and no immediate effects of the control interventions, further significant improvements would not be expected during the follow-up phase for the control group.

A final limitation to this study is the generalizability given the small number and limited population of participants. All three locations were private clinics in the northeast of the United States. Although specific demographic information was not obtained, the majority of people served by these clinics are Caucasian, well-educated, and of relatively high socioeconomic status. This study is unable to address whether the same effects would be seen in other contexts where this FFM training may be used, such as in a school or home setting, or with a different cohort, such as children of lower socioeconomic status. Some evidence of similar treatments have indicated that children living in poverty may respond more strongly than those above the poverty line (Husain & Mehta, 2011; Jaeggi, Buschkuhl, Jonides, & Perrig, 2008; Titz & Karbach, 2014), but they are less likely to receive treatment. The majority of the participants in the study had ADHD symptoms in the mild to moderately severe range, so it is also not clear how well children with more severe symptoms would respond.

To better understand the variables that contribute to the efficacy of this FFM training, different FFM training regimens should be tested in future studies. For instance, sustainability was only assessed with monthly booster sessions. Whether the FFM training improvements would be maintained if the child did not play the game at all after the 8 weeks of training was not addressed in this study. During the follow-up period, participants played the game once every 4 to 5 weeks, so it is not clear whether the FFM improvements seen with training would have been maintained without the booster sessions. It also remains unknown whether extending the FFM training beyond the 20 to 24 sessions over 6 to 8 weeks would have resulted in greater improvements or by how much training time could be reduced and achieve the same effects.

Although improvements in ADHD symptoms were observed after the FFM training, this study is not able to elucidate the mechanism of improvement. The EEG signal driving this system is attention-related and is hypothesized to be from the dorsal anterior cingulate cortex (dACC), which has been implicated as part of the executive attention circuit of the brain that may be underdeveloped in ADHD (Botvinick, Nystrom, Fissell, Carter, & Cohen, 1999; Bush et al., 1999; Castellanos et al., 2008). However, given that EEG has only coarse spatial information, it is difficult to

confirm this without an imaging study using a method with higher spatial resolution, such as functional magnetic resonance imaging (fMRI). This FFM training system is designed to cause the user to become more aware of their actual and shifting attention levels (scaled 0%-100%) through the speed of the video game's main character. The use of their own FFM of their individual attention levels to control their character in the game enables the participant to learn to gain greater control over distractions and impulse inhibitions and maximize sustained focused attention, among other skills. The repeated exercise of attentional control to achieve a future goal is expected to cause neuroplastic changes which would be expected to be evident in the dACC. Elements of the game are also designed to improve control over inhibition, so neural improvements would be expected in areas related to inhibition, such as the dorsolateral prefrontal cortex, inferior parietal cortex, and inferior frontal cortex (Aron, Robbins, & Poldrack, 2004; Garavan, Ross, Murphy, Roche, & Stein, 2002; Kana, Keller, Minshew, & Just, 2007). Further research is required to establish what neuroplastic changes occur with training and which aspects of the training are most effective for promoting these changes.

In conclusion, an FFM training system in a randomized, controlled study of 8- to 12-year-old children appeared to be an effective intervention for the treatment of ADHD and improving academic performance. The FFM system led to more significant and sustained (a) reductions in the severity of ADHD symptomatology and (b) improvements in academic performance abilities than the standard nonpharmacological intervention options used by the control group. This FFM training represents a potential new nonpharmaceutical intervention for the treatment of ADHD. The FFM training was also shown to improve objective measures of academic performance, demonstrating that what was learned in the FFM training effectively transferred to near real-world behavior (i.e., improved behavior at home) and to academic abilities that are far removed from the training itself.

Authors' Note

Certain electroencephalography (EEG) feed-forward technology of the *Atentiv™* System including the *CogoLand©* Gaming Software was developed in Singapore by researchers at the Institute for Infocomm Research; Agency for Science, Technology and Research (A*STAR); the Institute of Mental Health; and Duke-NUS Graduate Medical School.

Declaration of Conflicting Interests

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