Repeated Measures Evaluation of IonCleanse by AMD Footbath Relative to Changes in Autism Treatment Evaluation Checklist (ATEC) Scores for Individuals with Autism Spectrum Disorder (ASD)

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Abstract

A report of the results for a group of ASD patients with the introduction of IonCleanse by AMD footbaths as a treatment for improving Autism Treatment Evaluation Checklist (ATEC) scores over 60-days. A repeated measures model was used to evaluate changes in ATEC scores over two time-periods; 30-days and 60-days. At 30-days ATEC score reduced (improved) by 21% and at 60-days reduced (improved) by 11%. A total ATEC score reduction of 32%. The repeated measures and post-hoc analysis demonstrated statistical significance overall and for all sub-groups of the ATEC questionnaire.

Keywords: *ATEC, ASD, IonCleanse, Footbath, Detox*

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Introduction

Autism spectrum disorder (ASD) is a well-known neurodevelopmental disorder which affects social, communication and behavior (Dawson, Rogers, Munson, Smith, Winter, Greenson, Donaldson, and Varley, 2010). With the advancement of research, measuring treatment efficacy has become increasingly important. Accordingly, Autism Treatment Evaluation Checklist (ATEC) is an instrument designed by *Autism Research Institute* in order to assess the effectiveness of autism treatments (Remington, Hastings, Kovshoff, Espinosa, Jahr, Brown, Alsford, Lemaic, and Ward, 2007). There are many scales dedicated to people with ASD, but they usually focus on diagnosis and assessment of its severity. ATEC fills a gap in clinical practice and in research as it measures individual progresses along treatments.

ATEC is a scale inversely proportional to the improvement of the subject (the lower the score, the better the condition), and is divided into four subscales that cover all areas affected by autism: (i) Speech/Language/Communication (14 items), (ii) Sociability (20 items), (iii) Sensory/Cognitive Awareness (18 items) and (iv) Health/Physical/Behavior (25 items). It is a brief and easily applicable formulary that can be used to assess efficacy of any kind of intervention.

Importantly, ATEC was not designed for diagnostic purposes; only to measure changes in ASD severity, making it useful in tracking the efficacy of a treatment. Several prior studies recommend future research with other subjects or groups analyzing ATEC's sensitivity to change as an outcome measure.

The IonCleanse by AMD has been available in the market since 2002 and has successfully undergone electrical appliance safety testing. It received both Federal Communications Commissions (FCC) and Conformite Europeenne (CE) approvals (EMC Integrity, 2008). The IonCleanse by AMD detox footbath is used as a means to rid the body of toxins such as heavy metals.

A study conducted by the Centre for Research Strategies (2008) found a statistically significant reduction in aluminum and arsenic, but not changes in lead, mercury, or cadmium in whole blood of the participants after 12 weekly sessions. The Thinking Moms' Revolution (TMR) found a statistically significant improvement (reduction) in ASD children's ATEC scores. (Figure 1).

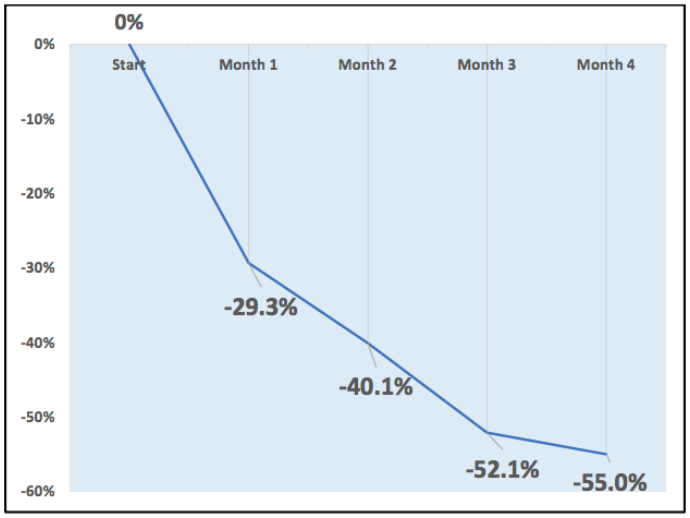


Figure 1

Dr. Kartzinel and A Major Difference developed this study to add to prior research on the effectiveness of the IonCleanse system relative to changes in ATEC scores for individuals with ASD.

Methods

Study Design

This was a non-randomized, nonblinded repeated measures trial conducted from June 18, 2018 (Day 0) through August 17, 2018 (Day 60) to measure ASD patients' change in ATEC scores after use of IonCleanse footbath.

To establish a baseline ATEC score, participants completed the questionnaire on day 0. Participants started use of IonCleanse by AMD on day 1 of the study. The protocol was to use the IonCleanse system for 3 days, take 1 day off, then repeated the process over a 60-day period. Participants completed the questionnaire at 30 days and again at 60 days, and their ATEC scores were calculated and recorded for analysis at the end of the study.

The therapy sessions were 20-45 minutes with the participant's feet in the IonCleanse footbath.

Participants

On June 18, 2018, 13 patients from Dr. Jerry Kartzinel's practice were recruited to participate in this study. Four patients were removed from the study due to noncompliance with therapy protocol. Participation in this study was voluntary and patients were able to discontinue at any time during the study.

Inclusion criteria required patients to be over 2 years of age with a clinical diagnosis of Autism Spectrum Disorder. Patients were excluded if they had any type of electrical implanted device; or on medications that a) control or mitigate life-threatening seizures; or b) support other life-sustaining functions (e.g. medications that regulate heartbeat).

ATEC Questionnaire

ATEC questionnaire is comprised of four subscales: (1) Speech/Language/

Communication, (2) Sociability, (3) Sensory/Cognitive Awareness, and (4) Health/Physical/ Behavior. These four subscales are used to calculate a total score that ranges from 0 to 179. A lower score indicates less severe symptoms of ASD, and a higher score correlates with more severe symptoms of ASD. The subscales provide survey takers information about specific areas of behavior which may change over time. It is a brief and easily applicable formulary that can be used to assess efficacy of any kind of intervention (Freire, Andre & Kummer, 2017).

Validation of ATEC Questionnaire

A study conducted to validate the ATEC using a test-retest reliability, and its concurrent validity by comparing it with the Childhood Autism Rating Scale (CARS) (Pereira, Riesgo, & Wagner, 2008) showed high test-retest reliability and high concurrent validity. This study concluded ATEC is a reliable and valid tool for evaluating treatments and improvements in people with ASD.

Mahapatra, Vyshedskiy, Martinez, Kannel, Braverman, Edelson, and Vyshedskiy, (2018) conducted a longitudinal assessment of individuals with ASD over 4 years to generate developmental norms for the ATEC. They concluded ATEC is an appropriate outcome measure for individuals with ASD.

Mahapatra, Khokhlovich, Martinez, Kannel, Edelson, and Vyshedskiy (2018) conducted another longitudinal study focusing on autism subgroups using ATEC. They concluded the use of ATEC supported the efficacy of caregiver-driven psychometric observation, which may be a viable alternative to using licensed technicians to assess the children.

Ionic Footbath Device

The IonCleanse by AMD ionic footbath was used for all sessions in the study. A Major Difference Inc. (AMD) donated an IonCleanse machine for the duration of this study. The

components of the ionic footbath include the device, an array, a power cord, plastic foot tub liners, and a plastic foot tub container (Figure 1). The device has a single preset program to generate a 70/30 mix of positive/negative polarity in a standard 30-minute session. The array is composed of an acrylic housing, a copper rod held in place with a bolt and fly nut, and a metal plate folded on itself several times (Figure 2) [18]. The side of the array is stamped with "316 SS" which we interpreted to indicate that the metal is composed of "316 grade stainless steel." The metal plates of the array have a limited lifespan and must be replaced after 30–50 sessions, with the "life" of a metal plate dependent on the mineral concentration of the water source.

FIGURE 1: Initial setup of IonCleanse SOLO footbath.

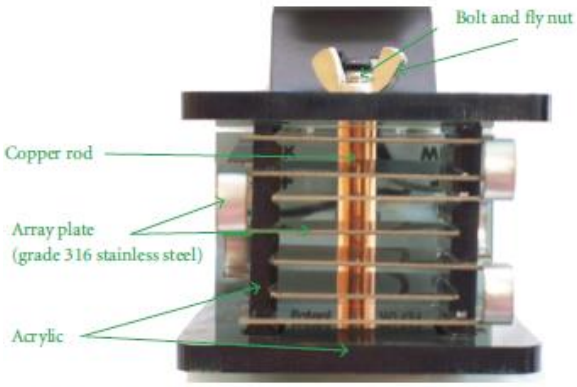


FIGURE 2: Close up of a new IonCleanse SOLO footbath array.

Collection of Evaluations

ATEC responses originated from participants voluntarily and freely completing ATEC evaluations from June 18, 2018 to August 17, 2018.

Evaluation of ATEC Score Changes Over Time

A one-way repeated measures ANOVA was conducted to compare the effect of IonCleanse by AMD on ATEC scores at 30 days and 60 days.

Results

The footbaths were well tolerated by all of the participants. There were no adverse events reported during the course of the study.

Results

There was a significant effect on ATEC scores, Wilks' Lambda = 0.45, F (2,39) = 23.364, p = .0001. Two paired samples t-tests were used to make post hoc comparisons between time measurements. A first paired samples t-test indicated that there was a significant difference in the ATEC scores from baseline to 30 days; t(8)=3.278, p=.011. A second paired t-test indicated there was no significant difference in ATEC scores from 30 days to 60 days; t(8)=1.502, p=.172. These results suggest that IonCleanse by AMD does have an effect on ATEC scores. Specifically, our results suggest that when individuals with a diagnosis of Autism Spectrum use IonCleanse by AMD for 30 days their ATEC scores decreases.

Post Hoc by Sub-Categories:

Speech/Language Communication

There was a significant IonCleanse by ADM effect on Speech/Language/Communication ATEC scores; t(8)=3.485, *p*=.008.

Sociability:

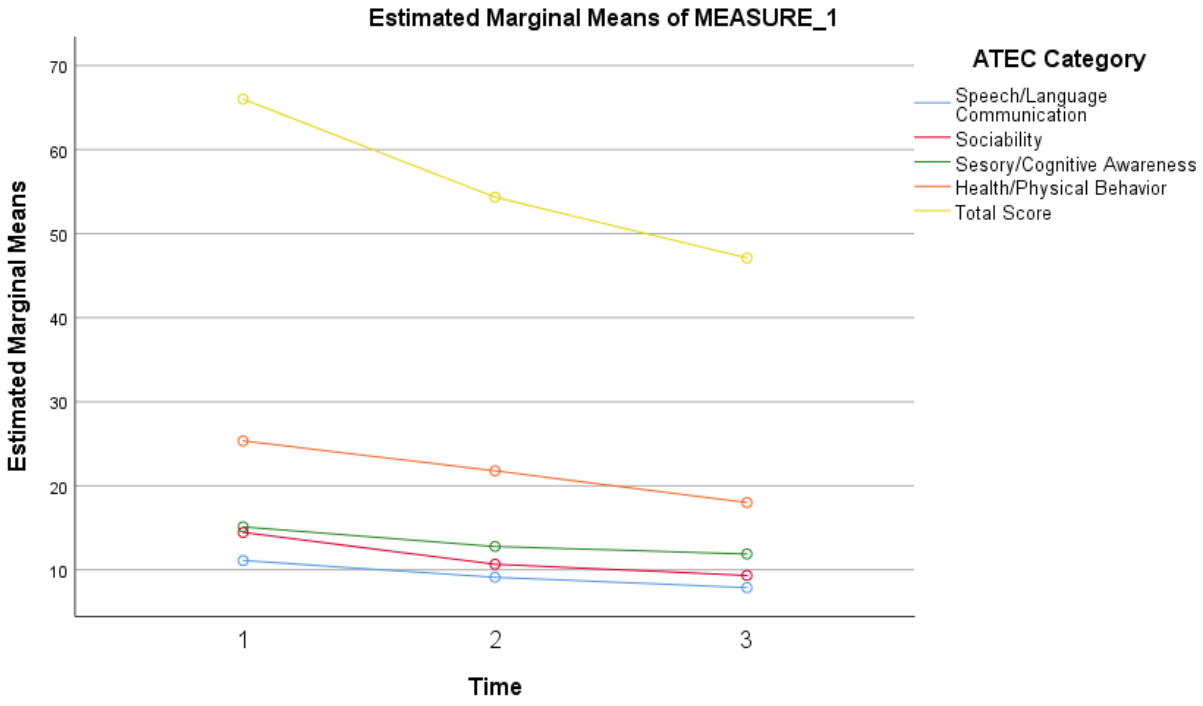
There was a significant IonCleanse by ADM effect on Sociability ATEC scores; t(8)=3.820, *p*=.005.

Sensory/Cognitive Awareness:

There was a significant IonCleanse by ADM effect on Sensory/Cognitive ATEC scores; t(8)=2.956, *p*=.018.

Health/Physical Behavior:

There was a significant IonCleanse by ADM effect on Health/Physical Behavior ATEC scores; t(8)=2.834, p=.022.



Conclusions

In this study we found evidence to support that IonCleanse by AMD ionic footbaths helped promote a decrease (improvement) in ASD individuals' ATEC scores. We tested the change in ATEC scores after use of IonCleanse ionic footbath over a 60-day period for nine ASD individuals. Eight out of the nine participants had a reduction in ATEC scores. The average ATEC score reduction was 32%. A limitation to the study was the low sample size. We recognize having a larger sample size could create a different outcome on ATEC scores. To provide further

support of our conclusions, it is recommended future studies be conducted by other subjects and groups of ASD individuals using footbaths.

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