The Thinking Moms' Revolution and IonCleanse® by AMD Study 1 and 2 Repeated Measures Analysis Report

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INTRODUCTION

An initial study was conducted by The Thinking Moms' Revolution (TMR) on the efficacy of treatments using the IonCleanse® by AMD Detoxification Footbath System. The IonCleanse by AMD utilizes ionic detoxification technology to reduce toxicity in children with autism spectrum disorders, thus reducing behaviors associated with autism.

The initial study was preceded by an established autism treatment evaluation survey to establish a baseline for each child's autism level. This evaluation was then repeated at the end of each one-month period. A total of 5 surveys per individual participant were completed over the four-month study period. The survey results were collected and compared in a prior study using mean changes and cumulative distribution curves.

This study's results determined that the children demonstrated a reduction in behaviors associated with autism.

The basic protocol specified the use of detox footbaths every other day, for a minimum of 15 minutes per session, over a period of four months from January through April 2015.

A sample population of 28 children, with their families, volunteered to participate in the 2015 TMR study. Four participants opted out of the study within the first 30 days. There were several families who had more than one child enrolled.

To determine if the prior study's mean changes over time are statistically significant, a repeated measures analysis was conducted using the same data.

FINDINGS

Study 1:

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean ATEC scores differed statistically significantly between time points ($F(2.331, 46.612) = 20.332$, $p < .0001$). *Post hoc* tests using the Bonferroni correction revealed that footbath treatments elicited an ATEC mean score decrease of 7.609 from baseline to end of 30-days treatment; however, this change was not statistically significant (p=.061). Footbaths from baseline to the end of 60 days elicited a statistically significant ATEC mean score decrease of 8.913 (p=.018). Footbaths from baseline to the end of 90 days elicited a statistically significant ATEC mean score decrease of 12.043 (p<.0001). And, footbaths from baseline to the end of 120 days elicited a statistically significant ATEC mean score decrease of 14.174 (p<.001). Therefore, we can conclude that the use of detox footbaths every other day, for a minimum of 15 minutes per session, elicits a statistically significant reduction in ATEC scores for children with ASD, regardless of their autism severity level.

Estimated Marginal Means of MEASURE_1
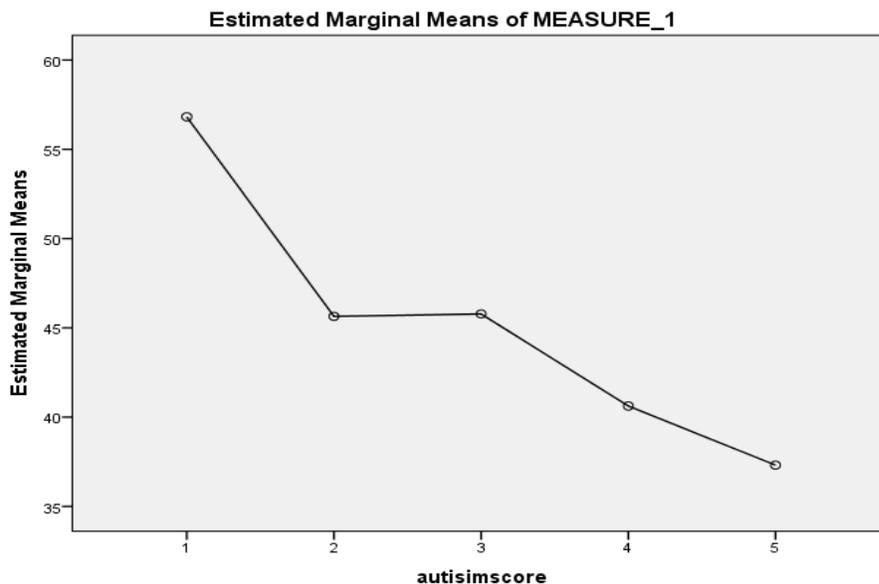
Study 2:

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean ATEC scores differed statistically significantly between time points ($F(1.986, 45.670) = 42.603$ $p < .0001$). *Post hoc* tests using the Bonferroni correction revealed that footbath treatments elicited a statistically significant ATEC mean score decrease of 14.375 from baseline to end of 30-days treatment (p=.002). Footbaths from baseline to the end of 60 days elicited a statistically significant ATEC mean score decrease of 21.775 (p<.0001). Footbaths from baseline to the end of 90 days elicited a statistically significant ATEC mean score decrease of 28.750 (p<.0001). And, footbaths from baseline to the end of 120 days elicited a statistically significant ATEC mean score decrease of 29.700 (p<.0001). Therefore, we can conclude that the use of detox footbaths for 3 days in a row, then one day off, then repeat protocol elicits statistically significant reduction in ATEC scores for children with ASD regardless of their session treatment times.

Note: session times were different based on child's age; however, each parent had the option to alter the frequency and session times. Any change in protocol was not captured in the data collection, so the session time was not entered as a variable in the ANOVA repeated measures analysis.

Session Time:	Ages 2-4	15-minute sessions
	Ages 5-7	20-minute sessions
	Ages 8-12	25-minute sessions
	Ages 13+	30-minute sessions

Estimated Marginal Means of MEASURE_1
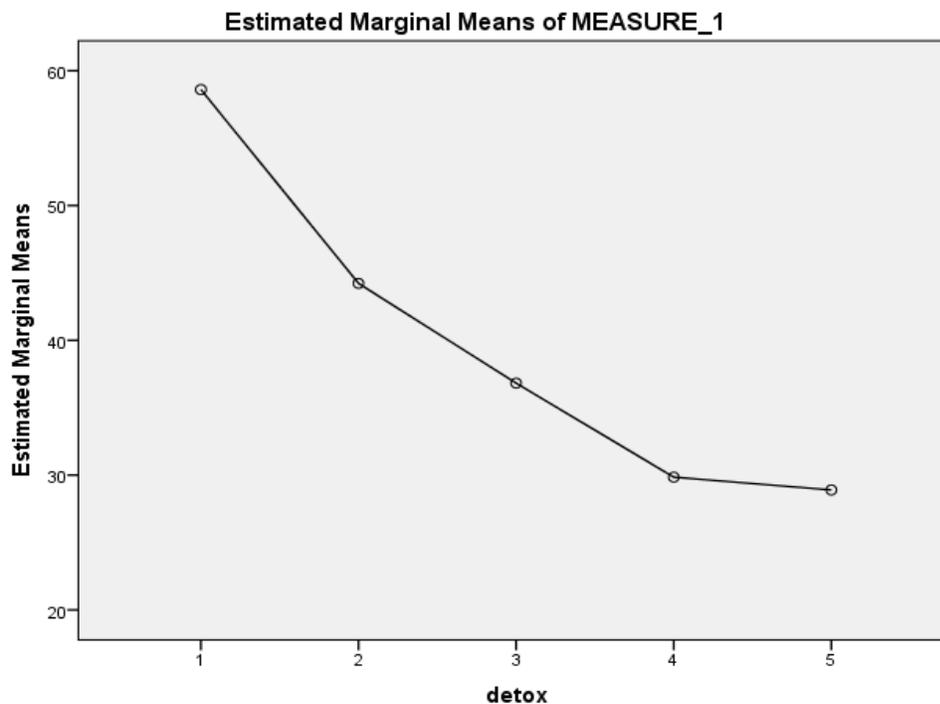
ANALYSIS DESIGN

An ANOVA with repeated measures is used to compare three or more group means where the participants are the same in each group. An example of this type of study would be when participants are measured multiple times to see changes to an intervention. Because each child participated in each of the four footbath sessions and was assessed using the ATEC tool after each session, an ANOVA with repeated measures design is appropriate for this data.

Assumptions

There are five assumptions that need to be met when running a repeated measures analysis.

1. The dependent variable should be measured at the continuous level; i.e., scores on a test.
2. The independent variable should consist of at least two categorically related groups or matched pairs.
3. There should be no significant outliers in the related groups.
4. The distribution of the dependent variable should be approximately normally distributed. A repeated measure ANOVA is quite robust to violations of normality.
5. Sphericity is met; that is, the variances of the differences between all combinations of related groups must be equal. However, ANOVA repeated measures are particularly susceptible to violating the assumption of sphericity. There are three separate analyses that can be utilized when sphericity is violated.
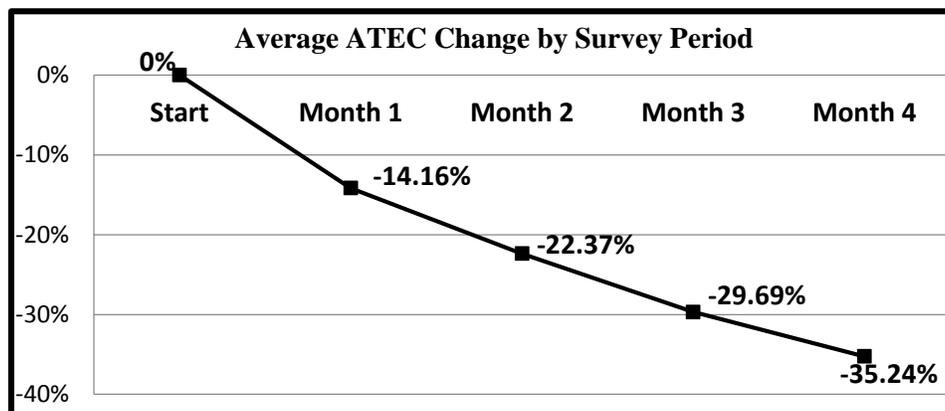
All assumptions were met. Greenhouse-Geisser was used to correct for sphericity. Data was analyzed using IBM SPSS Statistics version 23.

CONCLUSION

Study #1 and Study #2 provide strong, statistically significant evidence to support the theory that detoxification with the IonCleanse® by AMD helps children with autism spectrum disorders.

Raw Data – Study #1

Participant	Age	Gender	Baseline ATEC	30-Day ATEC	% Change	60-Day ATEC	% Change	90-Day ATEC	% Change	120-Day ATEC	Total ATEC Change
P1	2	M	83	63	-24.1%	83	0.0%	71	-14.5%	73	**-12.0%**
P3	3	F	87	46	-47.1%	40	-54.0%	39	-55.2%	36	**-58.6%**
P2	3	M	34	24	-29.4%	27	-20.6%	24	-29.4%	31	**-8.8%**
P4	4	M	55	26	-52.7%	30	-45.5%	34	-38.2%	20	**-63.6%**
P6	7	M	42	16	-61.9%	15	-64.3%	15	-64.3%	11	**-73.8%**
P5	7	M	45	35	-22.2%	31	-31.1%	30	-33.3%	29	**-35.6%**
P7	7	F	36	42	16.7%	43	19.4%	36	0.0%	37	**2.8%**
P11	8	M	30	29	-3.3%	20	-33.3%	20	-33.3%	22	**-26.7%**
P9	8	M	14	25	78.6%	15	7.1%	18	28.6%	15	**7.1%**
P12	9	M	5	5	0.0%	2	-60.0%	2	-60.0%	1	**-80.0%**
P15	9	M	29	13	-55.2%	9	-69.0%	9	-69.0%	8	**-72.4%**
P13	9	M	5	5	0.0%	5	0.0%	3	-40.0%	3	**-40.0%**
P14*	9	M	59	49	-16.9%	-	N/A	-	N/A	40	**-32.2%**
P18	10	M	60	57	-5.0%	52	-13.3%	46	-23.3%	48	**-20.0%**
P16	10	M	25	18	-28.0%	16	-36.0%	20	-20.0%	22	**-12.0%**
P17	10	M	39	35	-10.3%	30	-23.1%	29	-25.6%	37	**-5.1%**
P20	11	M	25	11	-56.0%	9	-64.0%	8	-68.0%	3	**-88.0%**
P19	11	M	30	30	0.0%	22	-26.7%	15	-50.0%	5	**-83.3%**
P22	11	M	62	62	0.0%	65	4.8%	49	-21.0%	34	**-45.2%**
P25	12	M	83	82	-1.2%	77	-7.2%	61	-26.5%	54	**-34.9%**
P28	12	M	58	54	-6.9%	54	-6.9%	51	-12.1%	45	**-22.4%**
P23	12	M	69	65	-5.8%	63	-8.7%	62	-10.1%	61	**-11.6%**
P24	12	M	4	4	0.0%	4	0.0%	4	0.0%	4	**0.0%**
P27	13	M	17	15	-11.8%	20	17.6%	14	-17.6%	12	**-29.4%**

Average ATEC Change by Survey Period

	Start	Month 1	Month 2	Month 3	Month 4
	0%	-14.16%	-22.37%	-29.69%	-35.24%

Raw Data – Study #2

Age	Gender	Base ATEC	30 Day ATEC	60 Day ATEC	90 Day ATEC	120 Day ATEC	120 Day ATEC Change
19	M	100	84	66	65	51	**-49.0%**
18	F	29	26	26	26	25	**-13.8%**
17	M	63	39	19	14	17	**-73.0%**
16	F	30	16	12	5	4	**-86.7%**
16	M	34	11	11	13	5	**-85.3%**
15	M	46	30	23	12	11	**-76.1%**
15	M	29	25	27	10	11	**-62.1%**
14	M	52	38	29	23	22	**-57.7%**
14	M	70	65	41	27	33	**-52.9%**
13	M	42	27	20	10	7	**-83.3%**
12	M	65	40	30	23	19	**-70.8%**
12	F	120	58	71	56	45	**-62.5%**
12	M	30	29	30	22	18	**-40.0%**
11	F	56	46	40	37	33	**-41.1%**
10	F	68	21	13	18	14	**-79.4%**
10	M	33	14	8	6	12	**-63.6%**
10	F	75	56	54	43	43	**-42.7%**
9	M	58	49	32	27	22	**-62.1%**
9	F	18	11	12	13	12	**-33.3%**
9	M	90	72	70	66	68	**-24.4%**
7	M	30	10	12	4	12	**-60.0%**
6	F	80	65	63	60	50	**-37.5%**
6	M	88	86	68	60	57	**-35.2%**
5	F	46	37	28	26	15	**-67.4%**
5	F	84	68	61	59	53	**-36.9%**
4	M	63	41	29	10	19	**-69.8%**
4	M	53	55	46	42	43	**-18.9%**

ATEC Change by Survey Period