
THE WWMG STUDY

IONCLEANSE® BY AMD

Treatment Effectiveness
for Individuals with Myasthenia Gravis

Debbie Norman
Women With Myasthenia Gravis (WWMG)
www.WomenWithMG.org
March 27, 2017

MSEC Background

This study required a way to numerically measure MG symptom severity. None of the currently available methods were complete enough to use for this purpose.

The Myasthenia Symptom Evaluation Checklist (MSEC) was created. The MSEC is now available at WomenWithMG.org for anyone that wishes to monitor their own MSEC score.

The MSEC is not a diagnostic checklist. It provides a score to be used for comparison at a later date. The lower the score, the lesser the individual's overall symptom severity.

The MSEC used for the study contained 3 sections:

- Symptoms (47 items)

- Accommodations/Assistive Devices (24 items)

- and a section for Additional Information that is non-scored.

A baseline MSEC was completed and submitted prior to the start of the study. Subsequent MSECs were completed and submitted after 30 days, 60 days, and 90 days.

WWMG 3 month Study

The purpose of this study was to evaluate the effectiveness of the IonCleanse[®] by AMD relative to MSEC scores for individuals with the autoimmune neuromuscular disease, Myasthenia Gravis. The study included 7 participants that completed the three months of IonCleanse[®] use according to the study schedule.

Symptom severity was scored using the Myasthenia Symptom Evaluation Checklist (MSEC). The higher the score, the more severe the MG symptom severity.

The study contained both male and female participants (adults and children).

The study included MG patients that were experiencing significant MG symptoms in spite of on-going care and were unhappy with their current level of functioning and quality of life.

The IonCleanse® by AMD is not a medical device and we did not require or suggest that anyone stop their current treatments.

The 3 month study began November 10th, 2016 and concluded on February 10th, 2017. Participants submitted an MSEC (Myasthenia Symptom Evaluation Checklist) prior to the start of the study. Additional MSEC scores were submitted after 30 days of use, 60 days of use, and 90 days of use.

IonCleanse® by AMD

The IonCleanse® by AMD is a painless, non-invasive total body detoxification and relaxation foot bath system that is used by children and adults. AMD, the manufacturer of the system, describes the IonCleanse® as follows (from www.amajordifference.com):

The IonCleanse by AMD's proprietary and patented technology results in only biocompatible electrical frequencies entering the water. Biocompatible frequencies elicit a relaxation response in the body; concurrently, they create an ionic field that cleanses and purifies the body through the healing power of ions.

The IonCleanse process ionizes the water, as H₂O is split into OH⁻ and H⁺ ions. These ions attract and neutralize oppositely charged toxins. After the process the user feels invigorated, refreshed, and relaxed.

More information regarding product details and company information can be found online.

Study Cleansing Protocol

Week One: one 10 minute session

Week Two: one 15 minute session

Week Three: one 15 minute session and one 20 minute session 4 days apart.

Week Four: one 20 minute session

Week Five: The schedule became cleansing every 3rd day and continued cleansing every 3rd day for the remainder of the 3 month study.

Week 6: we increased the session length to 25 minutes.

Week 9: we increased the session length to 30 minutes.

Week 10 : we increased the session length to 35 minutes.

Week 13: we increased the session length to 40 minutes.

Participants were instructed to do what they could to promote a relaxing environment during their sessions. It was recommended that they avoid talking to others, watching TV, using phones and other electronics, other outside stimulation and spend this time relaxing muscles and benefiting from the experience.

It was up to the participants what time of day they chose to cleanse. Most participants experimented until finding their preferred time of day to do their sessions. Most preferred evening or night sessions due to the relaxation benefits and improvement in MG symptoms they experienced after a long day. But they were free to choose whatever time of day fit their schedule and their personal experience the best.

AMD agreed to provide the IonCleanse® system for use at no cost to the study participants. Participants were able to purchase the IonCleanse® system at a discount at the conclusion of the study.

Results

Figure 1

IonCleanse by AMD Myasthenia Gravis Study Results

All participants below completed three months of IonCleanse use according to the study schedule. Symptom severity was scored using the Myasthenia Symptom Evaluation Checklist (MSEC). The higher the score, the more severe the MG symptom severity.

Starting MSEC	3 months of use MSEC	Percent Improvement
121	64	47 percent improvement
134	60	55 percent improvement
125	88	30 percent improvement
133	97	27 percent improvement
138	72	48 percent improvement
173	107	38 percent improvement
142	113	20 percent improvement
Total: 966	Total: 601	38 percent average improvement

Study done by Women With Myasthenia Gravis (WWMG).
The study included both male and female participants.

For more information visit: WomenWithMG.org

The 7 participants in the chart above included:

- 3 participants that are AChR positive
- 2 participants that are MuSK positive
- 2 participants that are seronegative

Four of the seven had been diagnosed with refractory MG.

Every participant that completed the 3 month study according to the study schedule experienced statistically significant improvement in MG symptomology.

Control Group Participants

The study contained a control group of MG patients with similar symptom severity to our study group.

The control group participants did not use the IonCleanse® by AMD and were followed during the same time period, using the same methods.

All participants in the control group were adult women. No men or children volunteered to participate in the control group.

The control group contained participants with a full range of antibody and refractory status, comparable to the study group.

The average change in MG symptom severity for the control group during the 3 month period was a 5 % increase in symptom severity.

In the control group 6 of the 17 participants showed an overall improvement in MSEC score during the study period, while 11 of the 17 participants in the control group experienced a worsening of MG symptom severity during the study period.

In contrast, every participant in the IonCleanse® by AMD study group that completed the 3 month study protocol as it was recommended, experienced an improvement in their MG symptom severity.

For a breakdown of individual control group scores, please see Figure 2 below.

Figure 2

Antibody Status	Base MSEC	Ending MSEC	% change in MG symptom severity
Unknown	114	121	6 % increase in severity
AChR positive	87	78	10 % decrease in severity
AChR positive	162	150	7 % decrease in severity
Unknown	141	164	16 % increase in severity
AChR & MuSK positive and Refractory	119	125	5 % increase in severity
Unknown	72	99	38% increase in severity
Seronegative and Refractory	118	125	6 % increase in severity
Seronegative	181	195	8 % increase in severity
Unknown	78	71	9 % decrease in severity
AChR positive	81	84	4 % increase in severity
AChR positive and Refractory	134	126	6 % decrease in severity
AChR positive and Refractory	84	78	7 % decrease in severity
AChR positive	60	52	13 % decrease in severity
AChR positive	151	160	6 % increase in severity
AChR positive MuSK positive	136	148	9 % increase in severity
AChR positive	66	84	27 % increase in severity
Unknown	109	135	24 % increase in severity

As with the study group, control group participants were chosen that had no known plans to begin any new MG treatments.

Neither group were asked to stop any existing protocols, nor were either group prohibited from adding additional protocols.

During the 3 month study, none of the IonCleanse[®] by AMD study group added any additional MG treatments beyond what they were using at the start of the study and some were even able to reduce MG treatments.

During the same period of time, 7 of the 17 control group members added additional MG treatments beyond what they were using at the start of the study.

The symptom severity within the IonCleanse[®] by AMD study group improved significantly more than the control group, even though the control group added additional MG treatments.

MG is a disease that commonly fluctuates in severity. While there were the expected fluctuations in both groups, the participants in the control group who saw an improvement in MG symptom severity did not see the degree of symptom improvement that the IonCleanse[®] by AMD study group did.

The most improved participant in the control group showed an overall improvement of 13% in MG symptomology.

During the same period of time, the most improved participant in the IonCleanse[®] by AMD study group showed a 55% improvement in MG symptomology.

GROUP COMPARISONS

Overall MG Symptomology

Figure 3

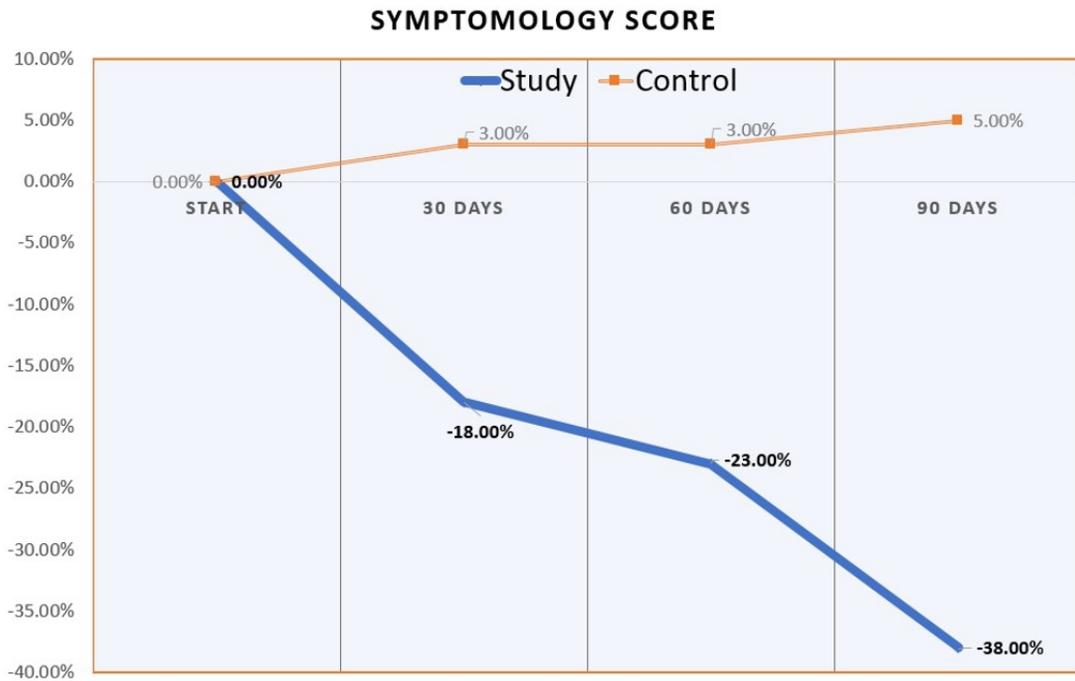


Figure 3 above illustrates the difference between the two groups overall MG symptomology.

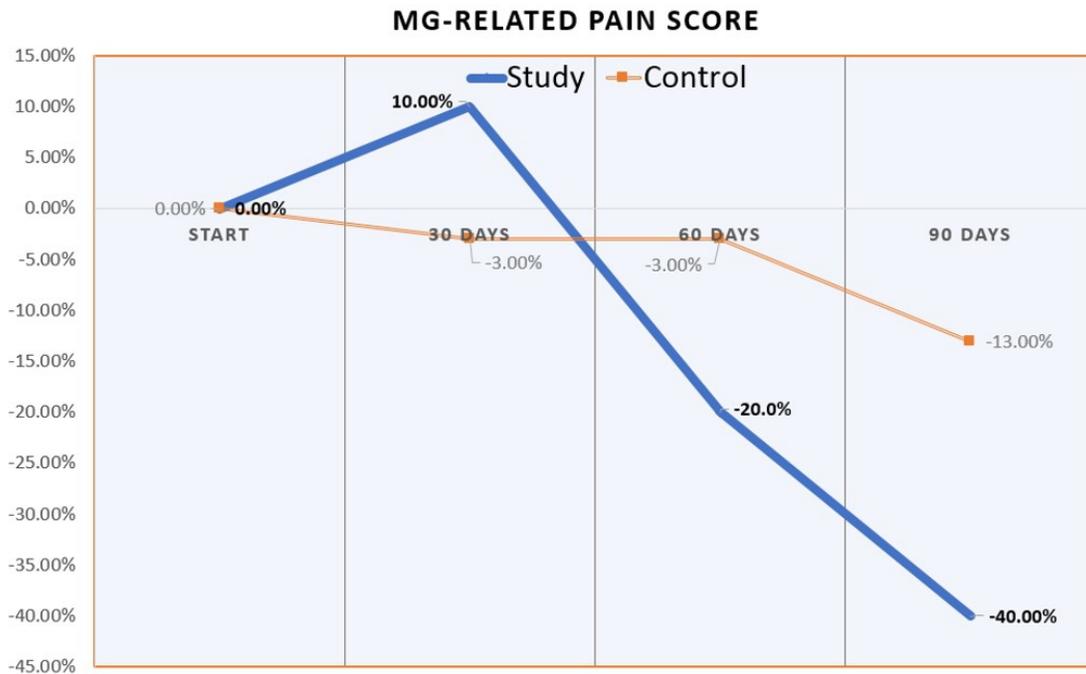
After 30 days the control group averaged a 3% increase in MG symptom severity, while the study group averaged an 18% decrease in MG symptom severity.

After 60 days the control group continued to average a 3% increase in MG symptom severity, while the study group averaged a 23% decrease in MG symptom severity.

After 90 days the control group averaged a 5% increase in MG symptom severity, while the study group averaged a 38% decrease in MG symptom severity.

MG-Related Pain

Figure 4



Throughout the study participants were questioned regarding their degree of MG-related pain.

Figure 4 above illustrates the difference between the two groups in MG-related pain.

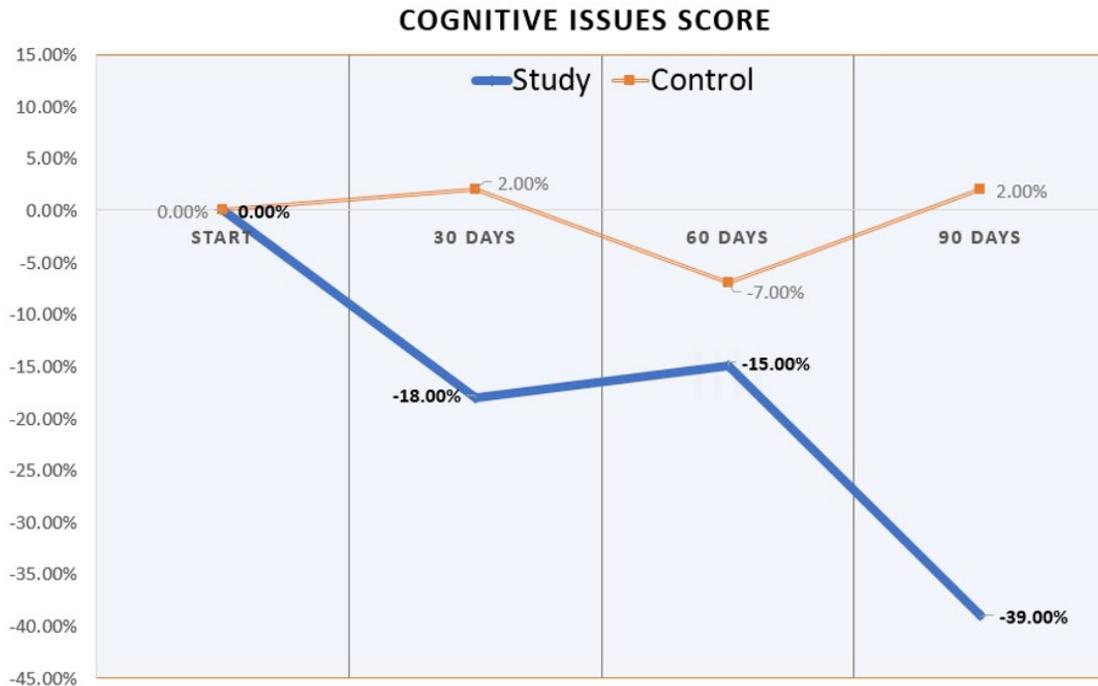
After 30 days the control group averaged a 3% decrease in MG-related pain, while the study group averaged a 10% increase in MG related pain.

After 60 days the control group continued to average a 3% decrease in MG-related pain, while the study group averaged a 20% decrease in MG related pain.

After 90 days the control group averaged a 13% decrease in MG-related pain, while the study group averaged a 40% decrease in MG related pain.

Cognitive Issues

Figure 5



Throughout the study participants were asked about their degree of cognitive issues (problems with finding the word they wanted to say, and overall “brain fog” and cognitive issues). Figure 5 above illustrates the difference between the two groups in cognitive issues.

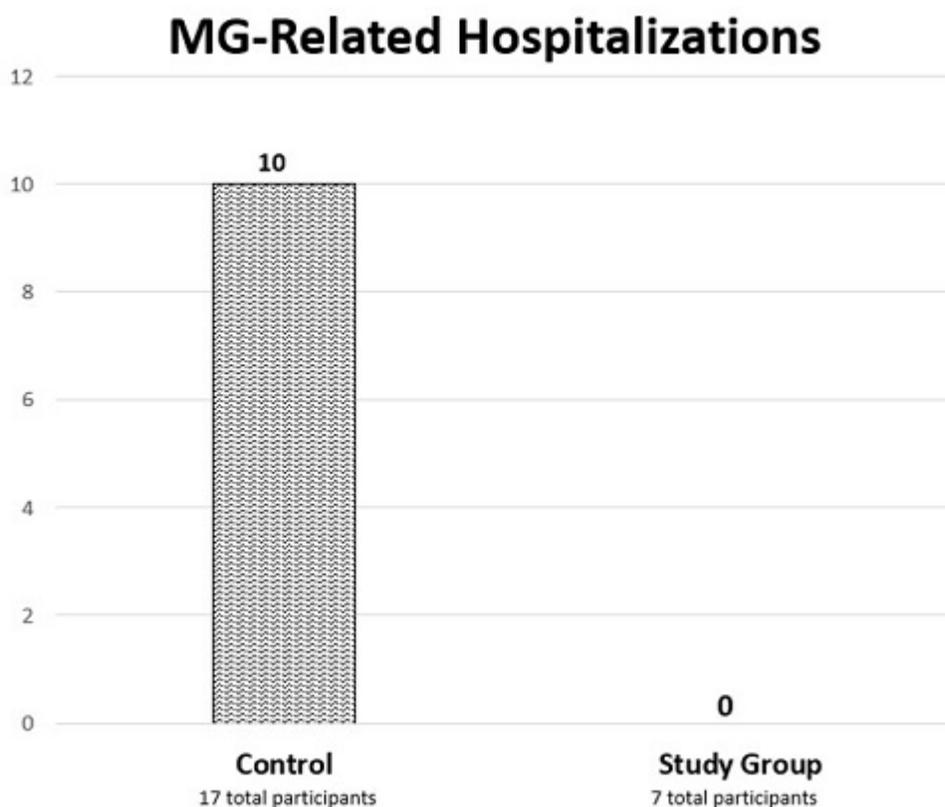
After 30 days the control group averaged a 2% increase in cognitive issues, while the study group averaged an 18% decrease in cognitive issues.

After 60 days the control group averaged a 7% decrease in cognitive issues, while the study group averaged a 15% decrease in cognitive issues.

After 90 days the control group averaged a 2% increase in cognitive issues, while the study group averaged a 39% decrease in cognitive issues.

MG-Related Hospitalizations

Figure 6



The number of MG-related hospitalizations were tracked throughout the study. Routine hospitalizations for plasmapheresis or IVIG that did not involve an MG flare or MG crisis were not included in the total for either group.

Figure 6 above illustrates the total number of MG-related hospitalizations in the two groups during the course of the 3 month study.

During the first 30 days the control group experienced 3 MG-related hospitalizations, while the study group experienced none.

During the second 30 day period the control group experienced 3 additional MG-related hospitalizations, for a total of 6 in the first 60 days, while the study group experienced none.

During the third and final 30 day period the control group experienced 4 additional MG-related hospitalizations, for a total of 10 MG-related hospitalizations in the control group during the 3 month study period, while the study group experienced none.

IonCleanse® by AMD Study Group **Individual Scores and Comments**

Female, Adult:

AChR negative
MuSK positive
diagnosed refractory

Medications and treatments for MG at start of study:

Plasmapheresis 1x every 2 weeks

MSEC score following 3 months of use reflected a 47% reduction in MG symptom severity.

Starting MSEC score: 121

Ending MSEC score: 64

Cognitive issues: 33% improvement

MG-related pain: 50% improvement

Plasmapheresis frequency – reduced to once every 4 weeks, without MG flare.

Participant reported:

Ability to relax: Improved

Sleep (quality, duration, etc.): Somewhat improved

Stamina: Improved

Ability to handle additional illness: Improved

Ability to increase activity level: Yes

Improvement in overall quality of life: Yes

COMMENTS:

"The first section of the study saw me through dental extractions and pneumonia. I feel I fought back against them better with the IonCleanse."
participant

"I had a very stressful day, did a session and had a great cleanse. I woke up feeling refreshed this morning."
participant

"I can now tolerate moderate amounts of alcohol to drink after 5+ years of being unable to drink at all, due to it flaring my MG."
participant

"My stamina is improving! Wednesday I went shopping for 3 hours. Thursday I cleaned my house, made appetizers for dinner, spent hours in a loud, crowded, family gathering. Friday I baked pies, pound cake, and did prep for dinner. Saturday I did my IonCleanse session at 9am, started cooking at 11am and collapsed into bed at midnight!!! I had 13 guests over for dinner and dessert. It was awesome!"
participant

"I went into pheresis this morning feeling like I could wait another week until treatment. My slurred speech is ever present, but I feel better in other ways."
participant after only one month of IonCleanse use

"My pulse rate and blood pressure have come down considerably. My brain fog is gone and I have been so productive!"
participant

"My hemoglobin level is now within normal range for the first time in FOUR years! I have been horribly and dangerously anemic for most of my life. I

had been told that pheresis was creating a red cell drain that my body was not recovering from. But with IonCleanse use it is!"

participant

"The single most exciting aspect of this treatment option is that it does not try to shut down my immune system in order to induce gains. THIS IS IT!! THIS is giving me my life back! I am so very grateful!!"

participant

"I cleaned in my basement for 7 hours yesterday. Today I am not stuck in bed too weak to eat. I am just a little sore and fatigued. I'm thinking about going shopping today!"

participant

"I love my IonCleanse! As a patient with the MuSK antibody, mestinon does not work in my favor. It is the 'helper' drug for symptom reduction in most MGers, and they adjust the dose as needed. The IonCleanse regimen is giving me a comparable tool to better health!"

participant

Female, Adult:

AChR positive

Medications and treatments for MG at start of study:

Mestinon

IVIg for 2 days every 4 weeks.

MSEC score following 3 months of use reflected a 55% reduction in MG symptom severity.

Starting MSEC score: 134

Ending MSEC score: 60

Cognitive issues: 50% reduction in cognitive issues

MG-related pain: none reported before or after study

IVIG frequency – unchanged but plans to discuss at next appointment with neurologist going to 1 day every 4 weeks, because she hasn't been feeling she needs the 2nd day.

Participant reported:

Ability to relax: Improved

Sleep (quality, duration, etc.): Improved

Stamina: Improved

Ability to handle additional illness: Improved

Ability to increase activity level: Yes

Improvement in overall quality of life: Yes

COMMENTS:

"I have had an amazing month as I look back."

participant at the end of 2nd month of use

"Day before IVIG and I rallied to get things done before then. Absolutely no question the session last night is responsible. I probably did too much, but I plowed through. I cleaned the kitchen and bath, did laundry, went out for a few groceries, took the dog for a short walk and prepared dinner!"

participant

"Normally I am not even able to get on facebook much during infusion week. This week I have been typing up a storm."

participant

"I have been doing things that I haven't been able to do in years!"

participant

"As I look back, I have had a great month over all. I have been out of the house more than I can remember in a long time, including a night out with friends listening to music and dinner out with others. The extra energy continued through Christmas. I had my granddaughter over for a sleepover and then suggested to my husband the next day that the three of us go

shopping and have an early dinner out. Yesterday, I made dinner for my daughter's birthday celebration and didn't get home until almost 10pm. WOW!"

participant

"I just remarked to my sister today, I feel better than I have in a long time."

participant 3rd month of use

"After IVIG my husband told me he was taking the dog for a walk and I surprised myself saying I wanted to go. I TOOK A WALK! I then stayed up until 11:30pm, with no nap required for IVIG flu. I typically sleep late the following day. Today I was up by 8:30 am! I cannot believe this! I have had 14 years of IVIG and never ever has this happened. My family never even calls me during IVIG week because they know I can't function."

participant

"I can't believe that we just walked at least a mile. You haven't been able to do this in years!"

participant's sister

Female, Adult:

AChR positive

Medications and treatments for MG at start of study:

none – due to severity of side effects

MSEC score following 3 months of use reflected a 30% reduction in MG symptom severity.

Starting MSEC score: 125

Ending MSEC score: 88

Cognitive issues: 40% improvement

MG-related pain: 100% improvement

Participant reported:

Ability to relax: unchanged
Sleep (quality, duration, etc.): Improved
Stamina: unchanged
Ability to handle additional illness: Improved
Ability to increase activity level: Yes
Improvement in overall quality of life: Yes

Female, Adult:

AChR positive
diagnosed refractory

Medications and treatments for MG at start of study:

Mestinon
Huperzine

MSEC score following 3 months of use reflected a 27% reduction in MG symptom severity.

Starting MSEC score: 133

Ending MSEC score: 97

Cognitive issues: 50% improvement

MG-related pain: unchanged

Participant reported:

Ability to relax: Improved
Sleep (quality, duration, etc.): Improved
Stamina: Improved
Ability to handle additional illness: Improved
Ability to increase activity level: No
Improvement in overall quality of life: Yes

COMMENTS:

"I think now that I am over the illness, I may see more gains. But I am thrilled that I didn't end up in the hospital in crisis with that nasty illness I had. Plus, I was able to get by without IVIG or plasmapheresis."

participant

Female, Adult:

AChR negative

MuSK not tested due to lack of insurance coverage for test.

Medications and treatments for MG at start of study:

Mestinon

Prednisone

MSEC score following 3 months of use reflected a 48% reduction in MG symptom severity.

Starting MSEC score: 138

Ending MSEC score: 72

Cognitive issues: 25% improvement

MG-related pain: 50% improvement

Participant reported:

Ability to relax: Improved

Sleep (quality, duration, etc.): Improved

Stamina: Improved

Ability to handle additional illness:

Not applicable due to contracting no illnesses during the study.

Ability to increase activity level: Yes

Improvement in overall quality of life: Yes

This participant was able to taper completely off of prednisone during the study.

COMMENTS:

"I love how easy it is to relax."

participant after first week of use

"I have not had any viruses since beginning cleansing which is awesome and amazing for this time of year!!"

participant after 30 days of use

"I am having productive cleanses. I am so pleased with the relaxation effects and the fact that I have still not displayed any viral effects of what is going around."

participant

"I am just amazed that I am still virus free. The cold has affected my limbs myasthenia wise as usual. But when I have a good day, the quality of that day has increased. It has been subtle, but I so feel it!"

participant after 60 days of use

"I am just so grateful!"

participant after 90 days of use

Female, Adult:

AChR negative

MuSK positive

diagnosed refractory

Medications and treatments for MG at start of study:

Plasmapheresis, 2 treatments every 4 weeks

CellCept

Prednisone

MSEC score following 3 months of use reflected a 38% reduction in MG symptom severity.

Starting MSEC score: 173

Ending MSEC score: 107

Cognitive issues: 50% improvement

MG-related pain: 50% improvement

Plasmapheresis frequency – Participant is no longer feeling a desperate need for plasmapheresis when it is due. She (with monitoring and permission of her neurologist) has reduced plasmapheresis treatments from a frequency of every 4 weeks, down to every 6 weeks. She continued to not feel the desperate need for plasmapheresis when it is due, that she used to feel without the IonCleanse® by AMD system. She is also gradually reducing her CellCept dosage with plans for further reductions soon.

Participant reported:

Ability to relax: Improved

Sleep (quality, duration, etc.): Improved

Stamina: Improved

Ability to handle additional illness: Improved

Ability to increase activity level: Yes

Improvement in overall quality of life: Yes

COMMENTS:

“I could breathe better during and after my session. I couldn't take a deep breath without a lot of pain when I started. Now I feel my head draining and I can breathe more deeply. Amazing!”

participant's comments about session while having pneumonia

“My IonCleanse session brought about a productive cough and I was able to cough up a lot of stuff out of my lungs. I was very pleased!”

participant's comments about subsequent session during pneumonia

“My severe depression is improving and I feel happy for the first time in a long, long time.”

participant

“Woo hooo!!! Had a neurology appointment today (after shopping at an outlet mall for almost 3 hours) and my neurologist couldn't believe the difference in me from 3 months ago!!”

participant

“My close friends and family can't believe the change in me... So it's not just subjective for me to say it. Others have objectively noticed as well!”

participant

“She is so much more energetic, like her old self.”

participant's husband

“I have never been so happy in my entire life!”

participant

Male, Adult:

AChR negative

MuSK negative

diagnosed refractory

Medications and treatments for MG at start of study:

Mestinon

Prednisone

MSEC score following 3 months of use reflected a 20% reduction in MG symptom severity.

Starting MSEC score: 142

Ending MSEC score: 113

Cognitive issues: 20% improvement

MG-related pain: unchanged

Participant reported:

Ability to relax: unchanged

Sleep (quality, duration, etc.): unchanged
Stamina: unchanged
Ability to handle additional illness: unchanged
Ability to increase activity level: No
Improvement in overall quality of life: No

Observations

Reduction in MG symptom severity was seen in AChR, MuSK, and seronegative participants.

Reduction in MG symptom severity was also seen in individuals with refractory MG, a subset of MG patients that generally do not respond well to currently available treatments.

The majority of participants reported improvement in ability to relax.

The majority of participants reported improvement in sleep.

The majority of participants reported improvement in stamina.

The study was conducted during a time of year when various illness are circulating in the general public and most of our study group experienced at least one illness during the study (including, colds, bronchitis, pneumonia, etc.). The majority of participants reported that they handled illness much better while using the IonCleanse® by AMD, than they typically would have in the past. Many reported being impressed that they went through respiratory infections, etc. without any significant MG flare, no hospitalizations, etc.

The majority of participants reported an increase in activity level due to using the IonCleanse® by AMD.

Participants on IVIG and plasmapheresis were able to begin extending their length of time between treatments. For example one participant went from

needing treatment every two weeks, to every 4 weeks, without experiencing any of the typical MG symptom flaring that they typically experienced at the end of just a two week wait. One participant began to reduce their prescription CellCept as well.

At the start of the study one participant's physician was considering removing CellCept from her treatment regiment due to severe liver issues. By the end of the third month of IonCleanse® by AMD use, she reported that her liver function tested within normal range and she was able to stay on her CellCept.

The majority of participants reported that they felt that the IonCleanse® by AMD improved their overall quality of life.

The difference in the IonCleanse® by AMD study group compared to the control group was significant.

Additional Participants

The following are the 3 participants who used the IonCleanse® by AMD for the entire three month period but were unable to perform the sessions at the study schedule due to outside interfering medical conditions (unrelated to MG) and/or personal/family obligations that prevented them from completing cleansing at the study schedule.

Due to lack of adherence to the study guidelines/cleansing schedule, we were unable to include them in the overall results. Their data is included below, but it must be known that these results were with limited IonCleanse® use.

Female, Adult

AChR positive
Diagnosed Refractory

Medications and treatments for MG at start of study:

Mestinon
CellCept
IVIg for 2 days every 14 days
Solu-Medrol
Prednisone

MSEC score following 3 months of use: basically unchanged

Starting MSEC score: 174

Ending MSEC score: 175

Participant experienced an unplanned, physician-directed, dramatic reduction in steroids in the first 30 days of the study. This resulted in a 15.5% worsening of MSEC score in the first month. Every month of use following the first month produced a gradual improvement in MSEC score, arriving back near baseline by the end of the three month period.

Participant had an outside medical issue, present prior to the study, that prevented IonCleanse[®] use within the study guidelines. Participant continued to use the IonCleanse[®] at a much reduced rate with slow, gradual, 1 minute increases in session length and completed the 3 month study period at this limited-use level.

Despite being unable to reach session lengths that were found to be therapeutic for Myasthenia Gravis within the 3 month study time frame, the participant reported experiencing gains in other non-MG areas. Including, but not limited to, improved liver function. The participant reports being pleased with the results and plans to continue using the IonCleanse[®] by AMD.

MG-related pain: 33% improvement
IVIg frequency: unchanged

Participant reported:

Ability to relax: Improved
Sleep (quality, duration, etc.): Improved
Stamina: Improved
Ability to handle additional illness: Improved
Ability to increase activity level: Yes
Improvement in overall quality of life: Yes

Female, Child

AChR negative
MuSK negative
Physicians suspected CMS (Congenital Myasthenic Syndrome) but she has tested negative for all currently known CMS genes. Her team of doctors are planning to test for the newly-discovered MG antibodies within the next 6 months.

Medications and treatments for MG at start of study:

None – with plan to possibly start steroids soon.
(The 3 month study began November 10th, 2016 and concluded on February 10th, 2017 and participant did not have to start steroids.)

MSEC score following 3 months of use reflected an 11% reduction in MG symptom severity.

Starting MSEC score: 54

Ending MSEC score: 48

Participant experienced personal/family obligations that prevented them from completing all sessions and turning in forms according to the study schedule. In spite of this, participant still saw some improvement in MG symptoms, a reduction in illness-related MG flares, and gains in other non-MG areas. Her mother believes that her improvement would be more than

11% had she not been coughing so much the last month of the study due to illness.

MG-related pain: 100% improvement

Participant reported:

Ability to relax: Improved

Sleep (quality, duration, etc.): Improved

Stamina: Improved

Ability to handle additional illness: Improved

Ability to increase activity level: Yes

Improvement in overall quality of life: Yes

COMMENTS:

"It was peaceful, amazing, awesome and warm."
participant

"The winter months are always worse. But since we've been doing the IonCleanse her MG is not as bad as it usually is this time of year."
mother of participant

"This is the first year that she has stayed well enough to be able to go to school through the whole month of December."
mother of participant

"She has a problem with regular bowel movements. Cleanses are helping with producing regular bowel movements."
mother of participant

"Had fever blister on lip that came up and went away all on it's own without any medication. Typically we must medicate."
mother of participant

"I feel like the IonCleanse has kept her from catching every cold and virus"

that has been going around. What she has caught has not been as severe. Some of our scores stayed the same, but that is amazing since she usually goes downhill in December, January, and February. She has had a few asthma flares but we have been able to control them and not needed steroids or hospitalizations.”

mother of participant following 2nd month of use

“She caught a bad cold that has turned into a sinus infection, normally this would put her into a tailspin with her asthma and end up possibly with an ER visit and being put on steroids. Her asthma has been under control completely which amazes me. She has a horrible sounding but productive cough. No wheezing at all and her airways are clear and open, according to her doctor. Her o2 levels are at a steady 98. This may sound odd: Yes she is sick, but she is 'normal kid' sick.”

mother of participant at end of 3rd month of use

Male, child

seronegative MG

Medications and treatments for MG at start of study:

Mestinon

Participant experienced personal/family obligations that prevented them from completing all sessions and turning in forms according to the study schedule. In spite of this, participant still saw improvement in MG symptoms, a reduction in illness-related MG flares, and gains in other non-MG areas.

MSEC score following 3 months of use reflected a 19% reduction in MG symptom severity

Starting MSEC score: 64

Ending MSEC score: 52

MG-related pain: none reported before or after study

Participant reported:

Ability to relax: Improved

Sleep (quality, duration, etc.): Improved

Stamina: Improved

Ability to handle additional illness: Improved

Ability to increase activity level: Yes

Improvement in overall quality of life: Yes

COMMENTS:

“He says that it feels great and he really enjoys it. I have been impressed that I can see the differences in his foot bath water and other family members we did sessions on.”

mother of participant

“The winter months are always worse. But since we've been doing the IonCleanse his MG is not as bad as it usually is this time of year. His facial muscles are getting stronger, but limbs seem slightly weaker. So far he is getting over colds quicker than normal. Since birth he has been hospitalized every 2 years at the same time of year. This year we were expecting a hospitalization and we have not had one. This is a huge improvement.”

mother of participant

“This is the first year he has stayed well enough to be able to go to school through the whole month of December.”

mother of participant

“This cold is the first major cold of the season, he normally has had several by now either ending up in the ER or a hospital stay. His asthma has been in check and so has his MG. He is sick, but he is 'normal kid' sick. Also he hasn't had to be on steroids either.”

mother of participant

“He has had 2 allergic reactions in the past 3 weeks. They were not as severe as in the past and his MG stayed in check.”

mother of participant

“Someone that sees him everyday at school said to me today that he seems healthier than he's ever been!”

mother of participant

Conclusion

The study aimed to test a theory that the IonCleanse® by AMD may reduce symptom severity in individuals with the autoimmune neuromuscular disease, Myasthenia Gravis.

- For participants that completed the 3 month study as scheduled, the overall average reduction in MSEC scores was 38% over a 90-day period.
- 100% of study participants who completed the 3 month study as scheduled, showed a significant reduction in MSEC scores.
- Improvement was seen in both male and female participants.
- Improvement was seen in both adults and minors.
- Improvement was seen in AChR positive, MuSK positive, and “seronegative” participants.
- Improvement was seen in those with refractory MG.
- Improvement was significant compared to control group.

Reduction in MG symptom severity is an important finding for any individual with myasthenia gravis. But especially for those with refractory MG, as this population is in especially dire need of new therapeutic options.

According to a study published in the Yale Journal of Biology and Medicine in 2013:

“Refractory MG patients represent a small but distinct group for whom exploring newer therapeutic approaches and immunopathologic differences is warranted.” [Ref. 1]

We also found IonCleanse® by AMD use brought about significant improvement in pain related to myasthenia gravis. MG-related muscle weakness and instability resulting in pain is an area often overlooked by many medical professionals. Yet it is commonly acknowledged among physical therapists and orthopedic physicians that are familiar with treating MG patients. We were pleased to find the IonCleanse® by AMD to be effective in helping with this issue, in addition to the more commonly associated MG symptoms.

Another MG symptom that is known, but less frequently discussed includes mild cognitive issues such as having difficulty finding the word one wishes to say, and general issues commonly referred to as “brain fog”. There continue to be physicians on local levels that tell patients that their mild cognitive issues are not related to their MG, in spite of overwhelming reporting of this by many patients in the MG community and published scientific evidence. [Ref. 2-6]

In study participants who followed the study schedule, we found that use of the IonCleanse® by AMD improved cognitive symptoms in every study participant.

Improvement ranged from 20% to 50%, with an average reported improvement in cognitive symptoms being 40%.

In an environment where so many MG patients currently struggle to find treatment that is effective at reducing symptoms, absent of intolerable side effects, and to which access is not blocked by insurance companies refusing to pay for treatments that are necessary to maintain safety and quality of life, the IonCleanse® by AMD can be an effective and worthwhile therapeutic tool for consideration by individuals with myasthenia gravis.

This study provides strong, statistically significant evidence to support the theory that IonCleanse® by AMD use helps reduce symptom severity in individuals with the autoimmune neuromuscular disease Myasthenia Gravis.

Further evaluations, including double-blind, randomized, placebo-controlled studies, are likely needed to gain acceptance into mainstream myasthenia gravis treatment programs. Scientists understand that observation can lead to new and improved treatment protocols. While this evaluation, which includes mostly empirical evidence, supports a particular thesis, it is our great hope that other credible research entities will attempt to replicate the study's findings in controlled, clinical environments. Parties interested in conducting further research should contact AMD directly.

References:

1. Joome Suh, BS, Jonathan M. Goldstein, MD, and Richard J. Nowak, MD, MS. Clinical Characteristics of Refractory Myasthenia Gravis Patients. Yale J Biol Med. 2013 Jun; 86 (2) 255-260.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670444/>
2. Chen W, Zeng X, Luo F, LV T, Zhou X, Bai J. The decreased expression of thioredoxin-1 in brain of mice with experimental autoimmune myasthenia gravis. Neuromuscul Disord. 2014 Aug; 24 (8): 726-35.
<https://www.ncbi.nlm.nih.gov/pubmed/24878227>
3. D Joshi, M Bhatia, S Gupta, M Tripathi, A Srivastava, S Jain. Cognitive evaluation in myasthenia gravis: A P300 and neuropsychological study. Neurology Asia 2006; 11: 97-102.
http://www.neurology-asia.org/articles/20062_097.pdf
4. Paul RH, Cohen RA, Zawacki T, Gilchrist JM, Aloia MS. What have we learned about cognition in myasthenia gravis?: a review of methods and results. Neurosci Biobehav Rev. 2001 Jan; 25 (1):75-81
<https://www.ncbi.nlm.nih.gov/pubmed/11166079>
5. Paul RH, Cohen RA, Gilchrist JM, Aloia MS, Goldstein JM. Cognitive dysfunction in individuals with myasthenia gravis. J Neurol Sci. 2000 Oct 1; 179(S 1-2): 59-64.
<https://www.ncbi.nlm.nih.gov/pubmed/11054486>
6. Iwasaki Y, Kinoshita M, Ikeda K, Takamiya K, Shiojima T. Cognitive dysfunction in myasthenia gravis. Int J Neurosci. 1990 Sep; 54 (1-2):29-33.
<https://www.ncbi.nlm.nih.gov/pubmed/2265963>

(end)