



Effects of a Phytonutrient Complex on Migraine: Comparison of Overall Episodes to Quality of Life Factors

Neil E. Wolkodoff¹, Gerald M. Haase², and Reginald W. Kaptyn³

¹Colorado Center for Health & Sport Science: Denver, CO. ²University of Colorado School of Medicine: Aurora, CO. ³Orthopedic Associates of Muskegon: Muskegon, MI.



ABSTRACT

PURPOSE:

- Quality of Life (QOL) issues are particularly distressing to migraineurs.
- Current drug therapies focus on episodes but have not always provided other satisfactory symptom improvement.
- Nootropic supplements such as Medium Chain Triglycerides (MCT) have demonstrated overall brain and cognitive benefits in published studies.
- This trial used a proprietary MCT-based nootropic supplement (Figure 1) and investigated the relationship between overall migraine episodes and QOL, utilizing an on-line survey tool for the 60-day intervention period.

METHODS:

- Prospective, randomized, double-blind, placebo-controlled trial of a patented phytonutrient complex using a 3:1 randomization ratio, 60 days.
- Thirty subjects (n=30) in the intervention cohort consumed the active compound, compared with ten (n=10) subjects in the placebo control group.
- The specially developed electronic response form allowed subjects increased safety in assessing their clinical status.

RESULTS:

- Episode number declined by 53%, from 11.6 to 5.4 per 30 days. ($p < .05$)
- Episode duration decreased from 260 minutes to 158 minutes. ($p < .05$)
- Self-rated QOL improved by 43% ($p < .05$).
- Decreasing migraine symptoms correlated positively with QOL improvement ($p < .05$), correlation value of 0.45, a moderate relationship.

CONCLUSIONS:

- A decrease in migraine episodes, duration and severity was positively linked to the self-rated QOL measure for migraineurs.
- A proprietary high concentration ingredient complex using phytonutrients produced significant improvements across a broad domain of the measured variables, especially with reference to decreased episodes correlating with improved QOL.

INTRODUCTION

Migraine affects over 40 million people in the U.S. It is the third most prevalent disease world-wide with 12% of the world population suffering from some form of migraine.

QOL is especially important for those suffering from chronic conditions like migraine. During most migraine episodes, migraineurs cannot function normally. Common QOL issues include decreases or dysfunction in critical thinking, conversation & communication, and adequate sleep. Overall outlook can improve adherence to positive behaviors such as regular exercise and dietary modification, having further enhanced benefits.

Traditional drug studies for migraine have only minimally touched on QOL metrics. As MCT compounds have demonstrated brain and cognitive benefits, the goal of this study was to determine if an MCT-based compound would simultaneously improve migraine symptoms and QOL.

METHODOLOGY

- Migraineurs were recruited who had had at least six migraine episodes per month.
- Study requirements included a consistent lifestyle and medication regimen.
- Potential subjects completed an extensive health history questionnaire. Documents were presented to the IRB for review and subject approval.
- The investigation was a prospective, randomized, double-blind, placebo-controlled trial of the specific, nootropic MCT complex.
- Forty subjects (n=40) fully completed the 30-day pre-intervention and 60-day intervention periods.
- The study employed a 3:1 randomization ratio.
- Thirty (n=30) chronic migraine symptom sufferers consumed the proprietary, active MCT compound.
- Ten (n=10) control subjects received a similar-appearing placebo.
- Product was consumed each morning, either placed in a liquid or meal.
- Instructions to participants included maintaining a consistent lifestyle, health factors, and medications while consuming both supplements.
- The symptom metric survey used an electronic response form to allow subjects increased safety in assessing their clinical status.
- Subjects received regular communication to determine both issues and compliance with the study.
- Results were compared for the 30-day period prior to the study, and the last 30 days of either consuming the intervention or control compound.

Figure 1: Product Label



RESULTS

Results and scores were tabulated for the pre-assessment 30-day period, and the last 30 days of the 60-day time frame. Mean scores, pre and post and significance are reported in Table 1, and specifically highlighted in Figures 2 & 3.

Table 1: Overall Results by Category, mean score and statistical significance.

Metric	Pre-value	Post-value	Change	% Change	Significance
Episodes per 30 days					
Control	8.8	8.3	-0.5	6	
Intervention	11.6	5.4	-6.1	53	0.0004
Minutes Per Episode					
Control	265	247	-18	7	
Intervention	260	158	-102	39	0.0105
Overall Quality of Life					
Control	58.7	60	1.3	2	
Intervention	46.73	67.03	20.3	43	0.00003

Figure 2: Episodes per 30 days, Pre and Post

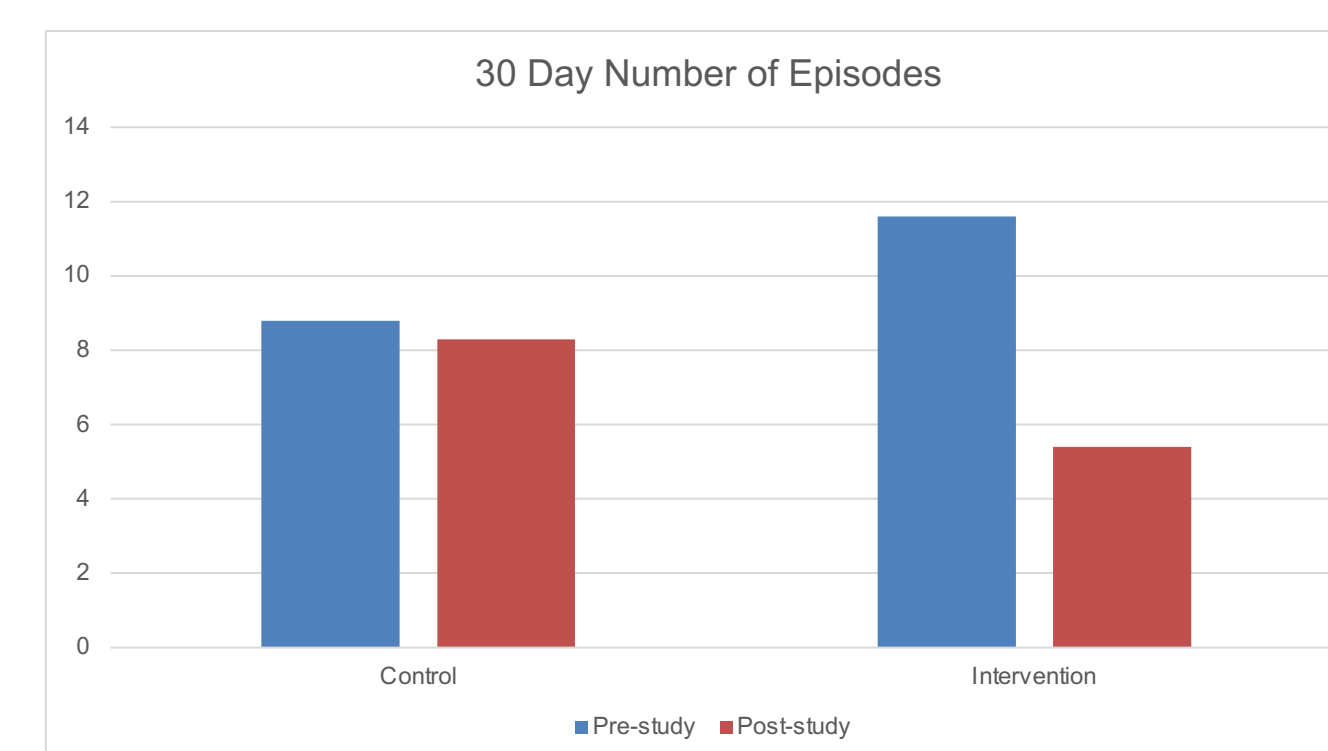
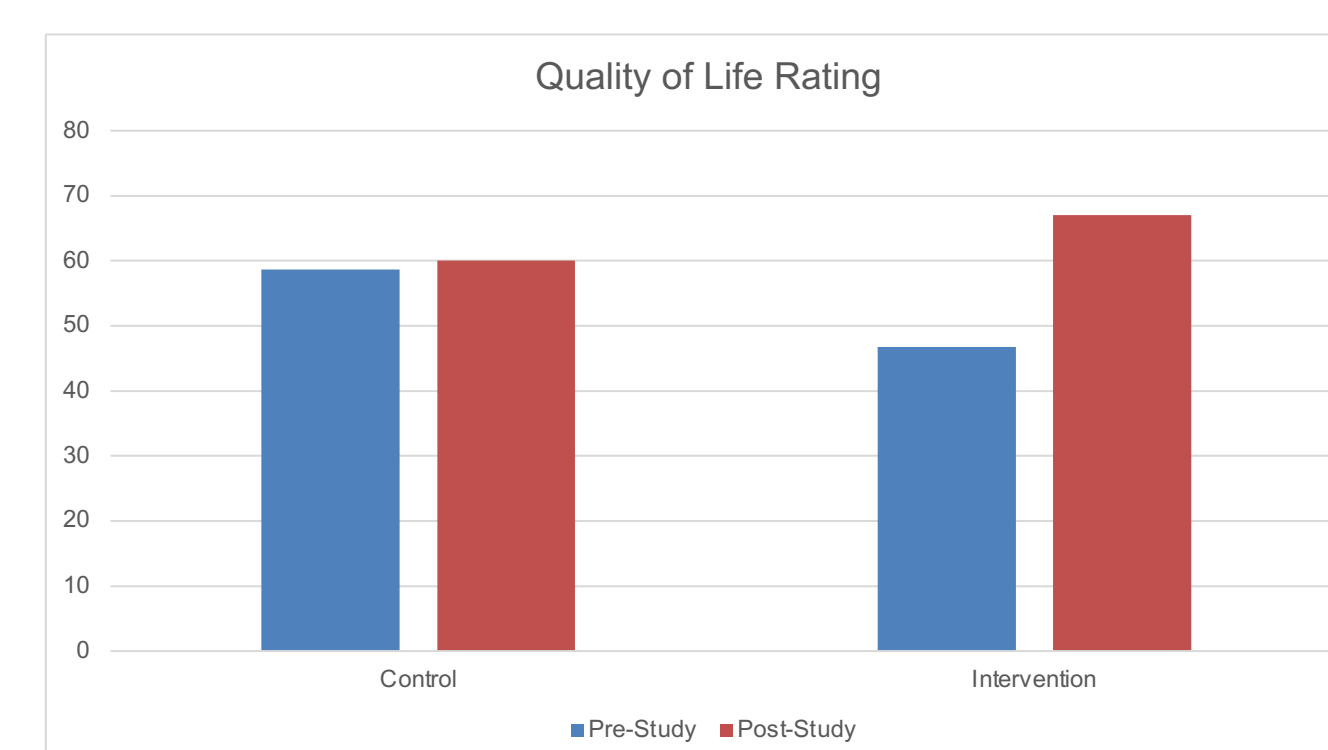


Figure 3: QOL ratings, Pre and Post



DISCUSSION/CONCLUSION

This study is the first to measure how a natural MCT-based supplement impacted migraine symptoms in comparison to changes in QOL. While the sample size is modest compared to pharmaceutical study numbers, the results were significant between the intervention group and the control group.

The intervention group significantly improved in the metrics of episodes and duration compared to the control group. In addition, intervention subjects also reported greatly improved QOL on the self-assessment scale. From a global perspective, this particular nootropic ingredient complex had significant benefits on the key metrics.

Two important observations result from this investigation. A nootropic MCT-based compound did aid migraineurs in the two areas critical from their perspective: reduced episodes and duration.

QOL, also important to migraineurs, significantly improved. The correlation to decreased episodes was measurable and statistically significant. This observed relationship highlights the interplay between episode reduction and improved perception of QOL.

These important results should generate further investigation on the impact of nootropic supplements and the relationship of episodes to QOL in migraineurs.

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Competing Interests

NEW has no competing interests. GMH and RWK are scientific advisors to the company.

Contact

Neil E. Wolkodoff, neil@cochss.com

Presentation Venue

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