

Clinical Summary

Evaluation of SPM Active® in high-frequency physical activity and training: summary of clinical experience

Introduction

Physical activity is an inflammatory challenge.^{1,2} Prolonged or intensive physical activity can lead to normal exercise-related skeletal muscle injury and a well-defined acute activation of the innate immune system^{1,2} that, if appropriately regulated, is integral to muscle repair and regeneration.¹

The balance between training and recovery is critical.³ Imbalance between training and recovery can lead to “functional or nonfunctional overreaching” and over time to “overtraining syndrome.” This imbalance can occur if, for example, vigorous exercise is repeated too frequently and exceeds the ability of the individual to recover and adapt.² Ultimately, this imbalance comes with increased fatigue, increased risk of mood disturbance and discomfort, and cardiac and immune system stress. The transition through these phases is enhanced when recovery periods and sleep are insufficient and nutrition support is poor.^{3,4}

The body has mechanisms to promote recovery and healing. The production of specialized pro-resolving mediators (SPMs) and their pro-resolving actions are necessary to return to homeostasis and support our wellbeing⁵ and are a critical component of the body’s inherent healing capacity in response to physical and environmental challenges.⁶

Plasma SPMs have been shown to increase in humans following exercise,^{2,7} and in a mouse model of stretching, SPMs are increased in connective tissue with stretching.⁸ It has been suggested that these pro-resolving mediators play a role in resolving the inflammatory response to physical activity.^{7,9} However, the ability of the body to produce SPMs may be compromised in certain individuals, for example those with excess adipose tissue.^{10,11} Also, emerging evidence suggests that the ability to produce SPMs in response to an environmental challenge may be reduced with age.⁶

The goal of this clinical evaluation was to assess the impact of SPM Active on bodily discomfort, mood, and quality of life in highly active individuals.

Individual patient experiences/case studies

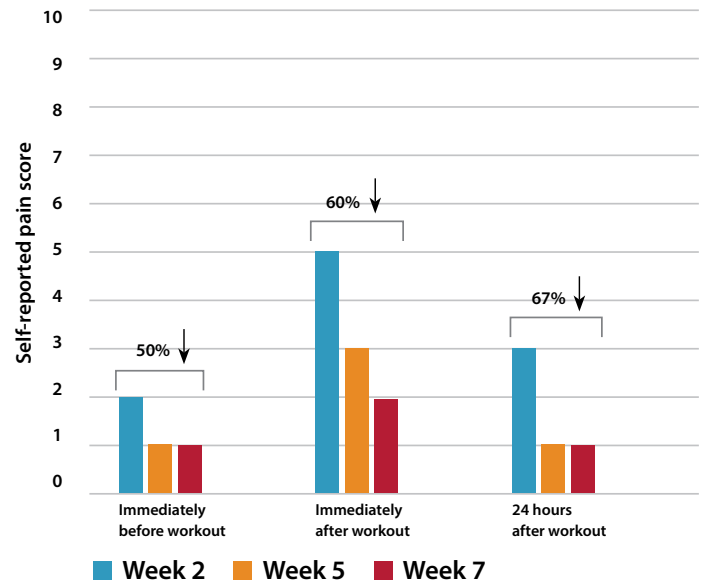
Case Study 1

A 34-year-old male cross-fit competitive athlete who engaged in a high-intensity long-duration training schedule 6 days per week presented with mild bodily discomfort and intermittent periods of reduced mental focus. The patient was not meeting best practice recommendations for dietary intake and was not currently taking other supplements that were reported. At baseline, temperature was recorded as 98.5° F, pulse as 88bpm, and blood pressure as 139/88mmHg (on second test). Body weight was 185 lbs. and height 70”, resulting in a BMI of 26.5kg/m². The patient was instructed to begin taking 2 SPM Active softgels each day (providing 1 g of active fractionated marine lipid concentrate standardized to 17-HDHA and 18-HEPE) without making any changes to regular diet and physical activity patterns.

Over the course of 8 weeks, the patient’s pain assessment questionnaires indicated that he experienced a reduction in normal exercise-related pain before and after a typical workout (Figure 1).

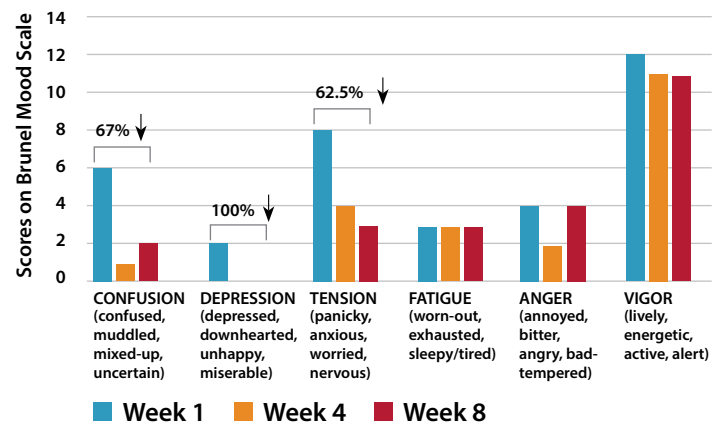
Figure 1: Improvements in Self-Reported Exercise-Related Pain Scores Before and After a Typical Workout

Subject was asked to rate pain on a scale of 0-10 with 0 being no pain and 10 being worst imaginable.



Scores on the Brunel Mood Scale (BRUMS) showed that he reported experiencing improvement in mood scores, including Confusion, Depression, and Tension (Figure 2). Other measures on this scale (Fatigue, Anger, Vigor) remained more stable.

Figure 2: Improvement in Mood Scores over 8 Weeks†



Scores on the MOS SF-36, a validated questionnaire reporting health-related quality of life, showed that Physical and Social Functioning remained high (maximum scores of 100 across visits), reflecting the fact that this was a relatively healthy, highly active, young patient. However, echoing the results of the BRUMS test, improvement in Emotional Wellbeing score was observed (56 to 84 over 8 weeks; max score 100).

Over the course of the study, the subject reported improvements in bodily discomfort. Blood glucose and kidney function tests stayed stable and within normal limits. Improvement in liver function tests was seen (AST was reduced 45 to 33U/L (reference: 10-40U/L), and ALT was reduced from 57 to 33U/L (reference: 9-46U/L) over 8 weeks. There was some increase in WBC and IL-6 at 8 weeks, which the attending physician felt may be suggestive of mild response to an environmental or physical trigger; however, TNF- α remained within normal limits throughout. Body weight and vital signs remained stable throughout the study.

Summary and physician impression: SPM Active supplementation for 8 weeks led to reduction in bodily discomfort following workouts and also improved mood and focus in this highly trained individual. The physician noted that he was a motivated and compliant participant, who, although highly functional without severe symptoms, was not thriving at baseline. Participant reported to physician that he was recovering better and could train better the next day.*

Case Study 2

A 48-year-old woman who competes biannually in a bodybuilding and fitness contest, which requires a frequent and intense training regimen, presented with fatigue, minimal recovery, compromised sleep patterns, bodily discomfort, intermittent reduced focus, and impatience. At baseline, blood pressure was 106/67mmHg, pulse was 50bpm, and temperature was 98.2°F. Body weight was 117 lbs. and height 5'4", with BMI calculated as 20.1kg/m². The patient was instructed to begin taking 2 SPM Active softgels each day (providing 1g of active fractionated marine lipid concentrate standardized to 17-HDHA and 18-HEPE) without making any changes to regular diet and physical activity patterns.

Over the course of 8 weeks, the patient reported experiencing an 87.5% reduction in fatigue (score reduced from 8 to 1) as assessed by the BRUMS tool. Some reduction in anger was also seen, with other outcomes remaining relatively stable.

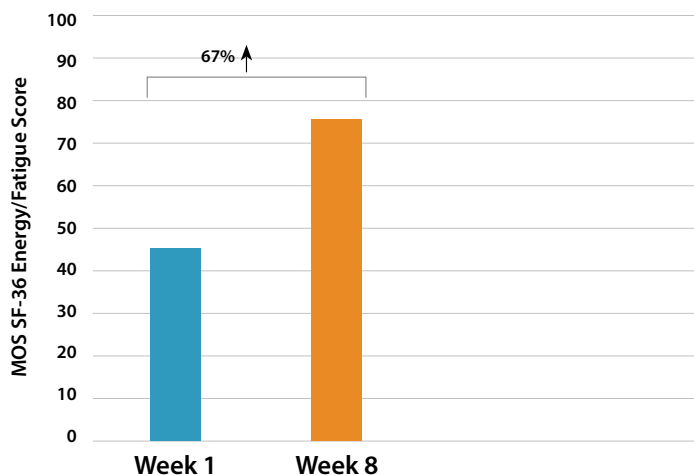
Similarly, MOS SF-36 tool showed an improvement in scores on the Energy/Fatigue scale, indicating that the patient was experiencing a reduction in feelings of fatigue (Figure 3).

References:

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* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Figure 3: Improvement in Energy/Fatigue Score Indicating Improvement over 8 Weeks



MOS SF-36 scores of Physical and Social Function remained stable and high throughout the study (max score 100), reflecting the relative health and high physical activity of the patient.

Pain before and after physical activity was moderate (3 out of 10) and remained stable over 8 weeks. Body weight remained stable over the 8 weeks. Physical exam revealed that the patient developed irritation and discomfort of the shoulder tendon at V2, which is very common with athletes competing in this type of events. No changes in vital signs were observed.

Summary and physician impression: Supplementation with SPM Active for 8 weeks led to a reduction in fatigue. Participant-physician interactions revealed that the patient was noticing an improvement in her overall wellbeing.*

Conclusions

In a case series[†] of individuals who engaged in regular and intense physical activity and training, taking SPM Active daily for 8 weeks led to the following:*

- Improvements in mood, mental clarity, stress, and fatigue
- Reduction in bodily discomfort after a typical workout

Notes:

Case studies conducted at Lazarus Wellness in Napa, CA, under the care of a licensed health-care practitioner, Ryan Lazarus, DC. IRB Approval for this study was obtained (Aspire IRB, Santee, CA).

Assessment tools used

The Brunel Mood Scale (BRUMS) is a tool used frequently to assess mood disturbances and has been used to evaluate mood before and after intensive training.³

[†]Rated each component by answering the question: In the past week, have you been feeling....

0) Not at all 1) A bit 2) Moderate 3) Enough 4) Extreme.

The scores for each component were summed within a domain.

Max score for domain = 36

Medical Outcomes Study 36 Item Short-Form (MOS SF-36) is a set of generic, coherent, and easily administered quality-of-life measures. These measures rely upon patient self-reporting and are now widely utilized by managed care organizations and by Medicare for routine monitoring and assessment of care outcomes in adult patients.^{1,2}

[†]Including two individuals. Case studies conducted at Lazarus Wellness.

Metagenics data on file, 2019.

