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RESPONSE TO LETTER

A Commentary on "Pain Reduction and Improved Vascular Health Associated with Daily Consumption of an Anti-Inflammatory Dietary Supplement Blend" [Response to Letter]

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Dear editor

We value the opportunity to respond to the commentary from Fang et al regarding our article "Pain reduction and improved vascular health associated with daily consumption of an anti-inflammatory dietary supplement blend".[1,2]

Inclusion Criteria and Study Design

The clinical trial was designed as an open-label pilot study on a dietary supplement, formulated to be accessible to the general public, rather than a drug targeted at a much smaller, very specific disease group. The nutraceutical supplement is being consumed across a broad and general population experiencing chronic pain. It was desirable for this initial pilot trial to reflect the normal consumer group. As such, it dictated a clinical trial design that was as inclusive as possible for people experiencing various types of chronic pain, not associated with a known illness, rather than a pharmaceutical study design that needs to be as exclusive as possible.

Heterogeneity Among Participants, Confounding Factors

Since the target consumer of this product is the general public, the most realistic study design needed to take that into account. In this study, aside from the relative openness of the inclusion criteria, the recruitment process included the collection of detailed health and lifestyle data on the participants, collected during the pre-recruitment process to exclude people with poor diet, lifestyle, substance abuse, and living under unstable socioeconomic conditions. All participants were asked to maintain their typical diet and lifestyle throughout the study, and report anything out of the ordinary that occurred during the study.

Safety and Efficacy of Long-Term Use

This pilot study was designed primarily as an efficacy study comparing two doses of the nutraceutical supplement, consumed daily for 8 weeks. Further studies of longer duration would be beneficial for documenting long-term efficacy and evaluate whether the reduced inflammation over time leads to reduced baseline pain to a level where the nutraceutical support for pain management may no longer be needed. It would also be of interest in future studies of other designs to include tracking of daily activity levels, dietary habits, and mood/psychological health. Such longer-term studies should also aim to document long-term safety; meanwhile, the safety of the single ingredients in this nutraceutical formulation is well documented in the public domain.

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Disclosure

At the time of the clinical trial, the author DEH was employed as the Director of Physician Education and Clinical Trials for the study sponsor, Research Nutritionals, LLC. GSJ reports no conflicts of interest in this communication.

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1. Fang A, Miao Y, Wang H. A commentary on "pain reduction and improved vascular health associated with daily consumption of an anti-inflammatory dietary supplement blend" [Letter]. *J Pain Res*. 2024;17:4197–4198. doi:10.2147/JPR.S507795
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