


LETTER

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# Letter to the editor: Study Summary - Randomized Control Trial of Omega-3 Fatty Acid Supplementation for the Treatment of COVID-19 Related Olfactory Dysfunction

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## Abstract

**Objectives:** To evaluate a therapeutic role for omega-3 fatty acid supplementation in the treatment of olfactory dysfunction associated with COVID-19 infection

**Trial design:** Randomized, double-blinded, placebo-controlled trial

**Participants:** Eligible patients are adults with self-reported new-onset olfactory dysfunction of any duration associated with laboratory-confirmed or clinically suspected COVID-19 patients. Exclusion criteria include patients with pre-existing olfactory dysfunction, history of chronic rhinosinusitis or history of sinus surgery, current use of nasal steroid sprays or omega-3 supplementation, fish allergy, or inability to provide informed consent for any reason. The trial is conducted at Mount Sinai Hospital

**Intervention and comparator:** The intervention group will receive 2000 mg daily of omega-3 supplementation in the form of two "Fish Oil, Ultra Omega-3" capsules (product of Pharmavite®) daily. The comparator group will take 2 placebo capsules of identical size, shape, and odor daily for 6 weeks.

**Main outcomes:** Each subject will take a Brief Smell Identification Test at study enrolment and completion after 6 weeks. The primary outcome will be change in Brief Smell Identification Test over the 6-week period.

**Randomisation:** Patients will be randomized by the Investigational Drug Pharmacy at the Icahn School of Medicine at Sinai via a computer-generated sequence in a 1:1 allocation to treatment or control arms.

**Blinding (masking):** Both participants and researchers will be blinded.

**Numbers to be randomised (sample size):** There will be 88 participants randomized to each group. A total of 176 participants will be randomized.

**Trial Status:** Protocol Version 1, 8/3/2020

Recruitment is ongoing, started 8/5/2020 with estimated completion 11/30/2020.

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**Trial registration:** The trial is registered on ClinicalTrials.gov with Protocol Identifier: [NCT04495816](https://clinicaltrials.gov/ct2/show/study/NCT04495816).

Trial registration: ClinicalTrials.gov, [NCT04495816](https://clinicaltrials.gov/ct2/show/study/NCT04495816). Registered 3 August 2020

**Full protocol:** The full protocol is attached as an additional file, accessible from the Trials website (Additional file 1).

**Keywords:** COVID-19, Randomised controlled trial, protocol, olfactory dysfunction, omega-3 fatty acid, smell loss

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-020-04905-y>.

**Additional file 1.** Full Study Protocol.

### Acknowledgements

Not applicable.

### Authors' contributions

DL, AF, PF – study design, subject recruitment. KG, AA, KL, SN – subject recruitment, literature review. MS, PC, AS, SG – study design, subject recruitment. AI – study design, study oversight. The author(s) read and approved the final manuscript.

### Funding

No funding was received for this study. Study drug and capsules were provided by Pharmavite®. Pharmavite® had no role in the design of the study and collection, analysis and interpretation of data and in the writing of the manuscript.

### Availability of data and materials

The final trial dataset will be accessible from the author on reasonable request. Contact David Lerner (e-mail [david.lerner2@mountsinai.org](mailto:david.lerner2@mountsinai.org)).

### Ethics approval and consent to participate

This study protocol was approved by the Institutional Review Board at the Icahn School of Medicine at Mount Sinai on 7/10/2020 (HS#:20-00511, GCO#20-1132 ISMMS).

Informed consent will be obtained from all participants. Only adults are included in the study.

### Consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

Received: 12 November 2020 Accepted: 15 November 2020

Published online: 23 November 2020

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Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

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