Dietary Supplements to Reduce Symptom Severity and Duration in People with SARS-CoV-2: Study Protocol for a Randomized, Double Blind, Placebo Controlled Clinical Trial

Supplementary Materials

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Table S1: Study Validation Template

Dietary Supplements for COVID-19: Data Validation Plan	**Tester**	**Test Date**	**Verifier**	**Verification Date**
Data Entry and Correctness: Correct data types for fields. No unbounded or missing data, and no extra points where the field is limiting.				
Data Entry Tracking: Shown at the bottom of every form in the electronic database field. This includes original data entry and future corrections.				
Security: Only authorized personnel with access to the network can access this password-protected file. Limitations will also be tested.				
Software and Hardware Verification: Certified and tested on both Windows 7 and 10 to ensure compatibility				
Functional Tests				
Normal or Expected Conditions Test: Tests must be performed on all critical variables.				
Abnormal or Unexpected Conditions Test: Unexpected values, or invalid data entry error messages, must be clear and shown to the user. Skipping rules, warnings, and error messages must be documented and tested.				
Branches, Data Flow, and Combinations of Inputs Test: includes navigation through the database.				
Stress Situations: performed to account for multiple users accessing the database at the same time: no overlapping, duplication, or crashing.				
Structural Tests				
Structural tests will be performed manually by the research team. Data exports will be checked for accuracy to the eCRF. This process will be individually documented.				

Legacy M, *et al. BMJ Open* 2022; 12:e057024. doi: 10.1136/bmjopen-2021-057024

2.0 Protocol Revision Chronology

Table S2: Protocol Revision Chronology

Version	Changes
1 - 2021-01-29	Original Protocol
2 - 2021-04-16	• Sponsor changed to Ottawa Hospital Research Institute (OHRI) • Allowed participants to take unused product to their local pharmacy for destruction • Added concomitant medications and stopping rules • Signatures now obtained through Adobe Sign
3 – 2021-05-04 (current protocol)	• Added eligibility criteria: participants must be tested by RT-PCR, participants must not have allergy to product ingredients • Added procedures for standard of care and hospitalization • Added official table for schedule of events • Indicated primary analysis in intention to treat • Added apparent decrease in uric acid levels as expected adverse event