

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2022/021

Scientific title of trial: Impact of "Entrasol Platinum" as an oral nutritional supplement on clinical, nutritional and functional outcomes of older adults with malnutrition or at risk of malnutrition: a randomized placebo-controlled trial

Date of commencement (enrolment of first participant): 23 January 2023

Progression: 6 months 1 year 2 years 3 years
At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruitment complete

Number assessed for eligibility: 115

Number recruited and allocated/randomized: 50

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1: 25 participants were allocated in the intervention

Arm 2: 25 participants were allocated in the control

Losses/exclusions after allocation/randomization (please edit as relevant):

Arm 1: 5 participants were lost to follow-up due to fractures, extended home visits and other acute illnesses

Arm 2: 3 participants were lost to follow-up due to fractures, and hospitalization.

3. Trial output

Date of trial completion ("last patient, last visit"): 25 August 2023

Final sample size: 42

Summary of Interim/Final data (if available):

Final data of anthropometric measurements, body composition parameters, biochemical parameters, functionality, and cognitive status has been collected and analyzed to provide comprehensive insights into the research

Abstract presentations of results at scientific meetings

Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
Impact of an oral nutritional supplement on improving body composition in older adults with malnutrition: a randomized controlled trial	<p>Prasani Wickramawardhane, Chamila Dalpatadu, Andrew P. Hills, Priyanga Ranasinghe, Ranil Jayawardena. (2023). Impact of an oral nutritional supplement on improving body composition in older adults with malnutrition: A randomized controlled trial. 18th Symposium on Nutri Indonesia in conjunction with 10th International Nutrition Symposium (Nutri 2023), page 38, 29th – 30th July 2023 in Jakarta, Indonesia.</p> <p>https://www.nutri2023.com/nutri-proceeding-book?utm_campaign=b2a9f880-ca05-43f7-8ce0-630820275b10&utm_source=so&utm_medium=mail&cid=c61a9cb1-b137-4296-baa2-fb71cfaedd13</p>
Impact of an oral nutritional supplement on improving body composition in older adults with malnutrition: A randomized controlled trial	<p>K. Weerasinghe, P. Wickramawardhane, C. Dalpatadu, P. Ranasinghe, R. Jayawardena. (2023). Impact of an oral nutritional supplement on improving body composition in older adults with malnutrition: A randomized controlled trial. Annual Congress of Sri Lanka Endocrinology (SLENDO 2023), page 29, 27th – 30th July 2023 at Hotel Shangri-La, Colombo.</p>
Improvement of nutritional status and body composition of older adults with malnutrition using an oral nutritional supplement: A randomized controlled trial.	<p>P. Wickramawardhane, T. Pathirage, D.T. Pathirana Hewage, R. Jayawardena. (2023). Improvement of nutritional status and body composition of older adults with malnutrition using an oral nutritional supplement: A randomized controlled trial. 8th Clinical Nutrition Annual Academic Sessions 2023 (SLMNA 2023), page 27, 26th August 2023 at Hotel Waters Edge, Colombo.</p>

	https://slmna.lk/uploads/uploads/9807a70b8957622c95d81bb268aa53eb.pdf
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Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
The impact of an oral nutritional supplement on body weight gain in older adults with malnutrition: an open-label randomized controlled trial: a protocol for a randomized controlled trial	Jayawardena, R., Wickramawardhane, P., Dalpadadu, C., Hills, A.P., Ranasignhe, P. (2023). The impact of an oral nutritional supplement on body weight gain in older adults with malnutrition: an open-label randomized controlled trial. Trials (accepted preprints), (https://doi.org/10.21203/rs.3.rs-2778010/v1).



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Name and signature of Responsible Registrant/
Principal Investigator

Date: 12 September 2023