

STUDY PROTOCOL

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The impact of an oral nutritional supplement on body weight gain in older adults with malnutrition: an open-label randomized controlled trial

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Abstract

Background The global aging population is expanding rapidly and many individuals have a particularly higher risk of malnutrition. Malnutrition can lead to impaired body function, morbidity, and mortality. Meeting nutritional requirements is a key strategy to minimize multiple debilitating adverse outcomes associated with malnutrition in the elderly.

Oral nutritional supplements (ONS) have been widely used as a dietary intervention for malnutrition in older adults. These supplements provide additional nutrients and calories to support nutritional requirements and have been shown to improve nutritional status, physical function, and quality of life in malnourished older adults.

Methods This is an open-label, randomized controlled, parallel-group study including 50 institutionalized older adults (aged > 60 years) with malnutrition or at risk of malnutrition, living in a selected elderly care institution in Colombo, Sri Lanka. The aim is to assess improvement in healthy body weight gain and body composition in older adults with malnutrition at risk of malnutrition by using an ONS. Older adults will be screened for malnutrition using the Mini Nutrition Assessment (MNA) tool and eligible participants randomized using the simple random sampling technique to intervention and control groups (1:1 allocation ratio). The intervention group will consume 200 mL of ONS before bed continuously for 12 weeks. The primary outcome is the percentage who achieved at least 5% weight gain in the intervention group compared to the control group. Nutritional status (anthropometric, biochemical, clinical, and dietary), body composition (dual-energy X-ray absorptiometry), frailty, functional capacity (hand grip strength, knee extension, and Barthel index) cognitive status (Montreal Cognitive Assessment), and physical activity will be assessed as secondary outcomes at baseline and at the end of the 12-week intervention. Some measurements (anthropometry, dietary, and functional assessments) will also be performed at the end of the 4th week. Data will be analyzed using SPSS V-23.

Discussion This study will determine whether the use of an ONS is effective in promoting healthy weight gain in older adults with malnutrition or at risk of malnutrition. In addition, investigating the impact of an ONS on multiple outcomes via clinical, nutritional, functional, and cognitive function will provide a more comprehensive understanding of the potential benefits of these supplements.

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