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#### **Original Study**

# Effects on Weight, Blood Lipids, Serum Fatty Acid Profile and Coagulation by an Energy-Dense Formula to Older Care Residents: A Randomized Controlled Crossover Trial



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#### ABSTRACT

Keywords:
Older people
energy-dense oral supplement
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coagulation factors

*Objectives*: Dietary intake in frail old adults is often lower than estimated needs. The aim of this study was to evaluate the effects of an energy-dense oral supplement on nutritional status, food intake, and physical function in residents living in care residential homes.

Design: Randomized controlled intervention trial with a crossover design.

Setting: Five care residential homes in the southern Stockholm area.

*Participants*: Older people living at care residential homes: age 65 or older, malnourished or at risk of malnutrition according to Mini Nutritional Assessment-Short Form (MNA-SF).

*Intervention:* Energy-dense formula (oleic and linoleic acid emulsion enriched with protein and micronutrients) (Calogen Extra, Nutricia) 30 mL distributed 3 times daily for 6 weeks.

*Measurements:* Body weight, 3-day food and fluid record, appetite rating, and physical function (ie, Short Physical Performance Battery, grip strength, and peak expiratory flow). Biochemical indicators of nutritional status, blood lipids, and serum phospholipid fatty acid (FA) profile.

Results: Twenty-eight participants completed the 2 phases of the crossover study; group A (n = 14, 87  $\pm$  6 years, 50% women) and group B (n = 14, 82  $\pm$  8 years, 71% women). The intervention periods combined resulted in significantly (P < .05) increased energy intake (238  $\pm$  544 kcal), weight gain (1.4  $\pm$  3.7 kg), improved appetite, relative reduction of saturated FA and increase in polyunsaturated FA, increased apoliporotein A, and reduced serum fibrinogen ( $-0.9 \pm 1.5$  g/L).

Conclusion: Distribution of an oleic and linoleic acid based fat emulsion enriched with protein and micronutrients (Calogen Extra) 3 times daily to old people in care residential homes improved nutritional status, had positive effects on fatty acid profile and blood lipids, and a potential antithrombotic effect. ClinicalTrials.gov Identifier: NCT01259999.

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Malnutrition has been reported in up to 55% of acutely hospitalized elderly, <sup>1</sup> in one-third of people living in assisted accommodation, <sup>2</sup> and in 30% of nursing home residents. <sup>3</sup> Dietary intake in frail and malnourished elderly is often lower than estimated needs due to the combined effects of the anorexia of aging and the presence of chronic disease. Evidence is piling to support the use of oral nutritional supplements (ONSs) in acutely ill, older, and undernourished patients. <sup>4</sup>

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Clinical benefits include significant reduction in mortality and complications, such as infections and pressure ulcers. Moreover ONSs, when used appropriately, improve energy and nutrient intake, nutritional status, and functional recovery. Nutritional supplements may be more effective than dietary advice for short-term improvement of body weight in individuals with disease-related malnutrition.

One barrier for ONS use among elderly is the volume that needs to be consumed resulting in low compliance. New low-volume, nutrient- and energy-dense ONSs seem to have higher acceptance and compliance, resulting in improvements in total energy intake and link to clinical benefits. Distribution of a small-volume oral energy-dense supplement, 3 times daily at the same time as medication

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rounds, resulted in increased energy intake and better appetite in geriatric in-ward patients. Both feasibility to distribute the supplement and the compliance to the product were successful. The result from this study initiated an idea to study frail individuals outside the acute hospital setting by a similar study protocol.

The aim of the present study was to evaluate the effects of an energy-dense oral supplement on nutritional status, fatty acid profiles, food intake, appetite, and physical function in older people living in care residential homes.

#### Methods

#### **Participants**

All residents living in 5 care residential homes in the southern Stockholm area were invited to participate in a randomized controlled trial. Inclusion criteria were as follows: age 65 years or older and informed consent to participate. Exclusion criteria were as follows: already supplemented with a fat emulsion, pancreatitis, fat malabsorption, too ill to participate, dysphagia, nonconsent for participation, cognitive dysfunction according to Short Portable Mental Status Questionnaire (SPMSQ, 0-2 points),  $^{10}$  well nourished according to Mini Nutritional Assessment-Short Form (MNA-SF, 12-14 points),  $^{11}$  and body mass index (BMI)  $\geq 28$ . Data were collected throughout 2010.

#### Study Design and Procedures

The study was controlled and randomized with a crossover design, illustrated in the flow chart (Figure 1). The residents who met the inclusion criteria were allocated to either start with intervention (group A) or start as controls (group B). For the randomization, permuted blocks of fixed length were used. Sealed envelopes were used to identify the group to which each recruited individual was

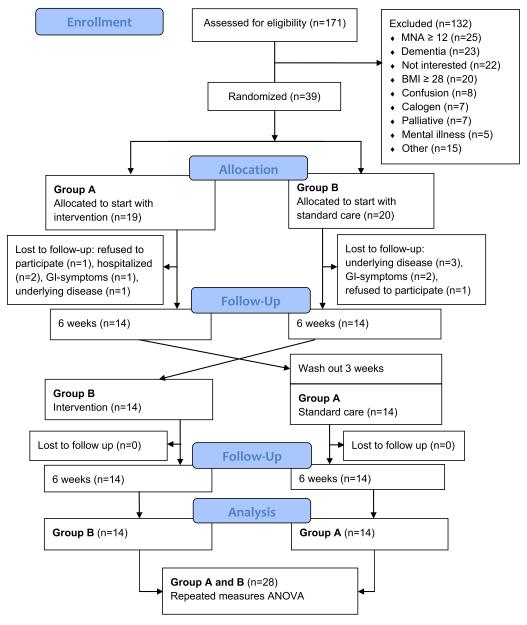


Fig. 1. CONSORT 2010 flow diagram. GI, gastrointestinal.

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