Abstract Details

Title: **The Effect of Oral Nutritional Supplement on Muscle Strength in Older Hip Fracture Patients (NUTRI-MUSCLES) – a Randomized Feasibility Trial for a Parallel RCT**

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Background and objectives

Malnutrition and dehydration are prevalent issues among older patients with hip fractures. Nutritional support is therefore recommended to continue after hospitalisation. This feasibility trial aimed to assess planned study methods, including recruitment and retention rates, in the NUTRI-MUSCLES study.

Methods

This parallel two-arm feasibility trial included patients ≥ 65 years old at nutritional risk admitted with a hip fracture at the orthopedic surgical ward at Herlev-Gentofte University hospital, Herlev, Denmark (December 2023-Februar 2024). Participants were randomized by computer-generated allocation sequences to receive oral nutritional supplementation twice a day for 12 weeks after discharge (intervention) or standard care (control). The primary outcome was recruitment and retention rate. Secondary outcomes were completement of data collection for the primary outcome (30-seconds chair stand test, 30s CST) and secondary outcomes in the definitive study (physical function, quality of life, blood samples, appetite, frailty, muscle strength and body composition). A completeness rate ≥80% was considered feasible.

Results

Out of 134 screened patients, 52 (39%) met the inclusion criteria, and 21/52 (40%) eligible patients accepted participation. Allocation resulted in 10 participants in the intervention groups and 11 in the control group. Prelimiany findings showed a retention rate of 17/21 (81%). Reasons for withdrawal included regretting participation and feeling overwelmed by current situation. At baseline, 4/21 (19%) could perform the 30s CST (using armrests) while all secondary outcome data collection was completed. Preliminary follow-up data showed that 7/7 (100%) could perform the 30s CST (1/7 used the armrests), and blood samples were obtained for 5/7 (71%), with succesfull data collection for all other secondary outcomes. No adverse events were reported.

Discussion

Recruitement and retention rates seem adequate compared to similar studies. The majority of planned methods for baseline data collection appear feasible with completeness ≥ 80%. Results from the 12 week follow-up will be presented at the conference. The definitive study is currently recruting and aims to include a total of 124 participants.

Trial registration: ClinicalTrials.gov identifier: NCT05556876.
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