

Preservation of Lean Mass upon Combined Lifestyle Intervention in Older Adults with Obesity and Type 2 Diabetes During 6-Months Follow-Up After RCT (PROBE Study)

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Objectives: Weight loss is a key element in the treatment of obesity and type 2 diabetes (T2D), but also a risk factor for lean mass (LM) loss in older adults. We evaluated whether a whey protein drink enriched with leucine and vitamin D preserved LM during 3-month lifestyle intervention and whether effects sustained during 6 months follow-up after intervention (FU).

Methods: 123 older adults (66 ± 6 y) with obesity (BMI 34 ± 4 kg/m²) and T2D participated in a 3-month lifestyle intervention with dietary advice (-600 kcal/d) and resistance exercise ($3 \times$ /wk). In this double-blind RCT (PROBE) subjects were randomised to receive $10 \times$ /wk a test (21 g protein) or isocaloric control (0 g protein) drink. LM, appendicular muscle mass (AMM), leg muscle mass (LMM), and fat mass (FM) were assessed with DXA. Mixed linear model analysis was used with baseline value in the outcome vector and adjustment for

stratification factors sex and SU-derivate use. Data represent EMM \pm SE (within group) or 95% CI (between groups).

Results: 105 subjects completed intervention and 76 subjects participated in FU. At 3 months, body weight (-2.2 ± 0.4 kg, $P < 0.001$, test; -2.9 ± 0.4 kg, $P < 0.001$, control) and FM (-2.6 ± 0.4 kg, $P < 0.001$, test; -2.5 ± 0.4 kg, $P < 0.001$, control) were reduced without differences between groups. LM and AMM were increased in test ($+0.57 \pm 0.27$ kg, $P = 0.03$; $+0.39 \pm 0.13$ kg, $P < 0.01$) and unchanged in control (-0.35 ± 0.26 kg, $P = 0.18$; $+0.03 \pm 0.12$ kg, $P = 0.80$), with significant difference between groups ($+0.92$ kg, 95% CI 0.19–1.65, $P = 0.015$; $+0.36$ kg, 95% CI 0.01–0.71, $P = 0.047$). At FU (without test or control drink), the difference in LM and AMM between groups had disappeared while both groups still had significantly improved body composition compared to baseline, as reflected by decreased FM (-2.4 ± 0.4 kg, < 0.001 , test; -2.6 ± 0.4 kg, < 0.001 , control) and increased or preserved LM ($+0.88 \pm 0.32$ kg, 0.007; $+0.54 \pm 0.32$ kg, 0.09) and AMM ($+0.46 \pm 0.15$ kg, 0.002; $+0.31 \pm 0.15$ kg, 0.03).

Conclusions: Use of a whey protein drink enriched with leucine and vitamin D during a combined lifestyle intervention showed beneficial effects on lean mass in older adults with obesity and type 2 diabetes. Preservation of lean mass was sustained after 6 months follow-up, without differences between treatment groups.

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