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A multicomponent intervention consisting of exercise, proteins and omega-3 supplementation to improve sarcopenia in community-dwelling older adults: Lessons learned from a 5-armed randomized controlled feasibility trial

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ABSTRACT

Background: Anabolic interventions, including physical exercise, proteins and omega-3 polyunsaturated fatty acids (PUFAs) supplementation, have shown effectiveness in improving sarcopenia outcomes. However, data on their combined effects in older adults with sarcopenia remain limited.
Objectives: To assess feasibility, acceptability, and preliminary effects of a multicomponent intervention combining individualized home-based exercise, proteins, and/or omega-3 supplementation.
Design: Parallel five-armed randomized assessor-blinded controlled feasibility trial with triple-blinded supplementation.
Participants and setting: Community-dwelling older adults (≥65 years) diagnosed with sarcopenia (EWGSOP2-criteria) from the Exercise and Nutrition for Healthy Ageing (ENHANce) study. The ENHANce study was registered on ClinicalTrials.gov (NCT03649698).
Intervention: Participants were randomized into 5 groups: 1) Exercise, 2) Proteins, 3) Exercise+Protein, 4) Exercise+Protein+Omega-3, and 5) Control group.
Measurements: Feasibility was assessed via eligibility, recruitment, retention, and data completion rates. Acceptability was evaluated through participants' feedback, adherence, and safety. Effects were measured by changes in sarcopenia outcomes after 12 weeks.
Results: Fifty-eight participants (76.2±6.6years,♀:65.5%) were included (Exercise,n=9;Protein,n=12; Exercise+Protein,n=13;Exercise+Protein+Omega-3;n=12;Control,n=12). Feasibility was low, with a recruitment rate of 2%. Acceptability was moderate, with most participants completing the planned assessments and reporting positive experiences such as feeling stronger and more aware of the importance of physical activity and nutrition. However, many found the study procedures demanding, and many experienced difficulties with the protein supplements. Adherence varied widely across interventions. Safety was high, with no significant adverse effects reported. The interventions showed potential to improve chair stand test (CST), Short Physical Performance Battery (SPPB), muscle mass and quadriceps strength.
Conclusion: A multicomponent intervention to treat sarcopenia showed low feasibility, moderate acceptability, and high safety. Preliminary efficacy results showed that exercise with protein supplementation may improve physical function. Adding omega-3 PUFA might offer further benefits for muscle strength and mass, but should be confirmed in larger studies. The insights and the practical challenges in the ENHANce study inform future sarcopenia intervention designs.

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1. Introduction

Sarcopenia, defined by the loss of muscle strength, muscle mass, and physical performance, affects up to 33% of individuals over the age of 65 years [1]. This condition impairs physical function, mobility and dependence, posing a significant health burden to the aging population [2–4].

Physical exercise, particularly resistance training, is a well-established cornerstone of sarcopenia management, improving muscle mass, strength, and overall physical performance [5]. Moreover, protein supplementation, alone or in combination with exercise, has also shown moderate evidence in improving sarcopenia outcomes [6–8]. Additionally, there is also an increasing interest in the use of omega-3 polyunsaturated fatty acids (PUFA) supplementation in the prevention and treatment of sarcopenia [9].

Despite this growing body of evidence supporting the effects of interventions to address sarcopenia, several research gaps remain. First, the combined effects of protein supplementation and resistance training is not fully elucidated in older adults with well-defined sarcopenia. Further research is needed to determine the potential benefits of these combined interventions. Moreover, the additive or synergistic effects of incorporating omega-3 fatty acids alongside resistance training and protein intake have not been fully examined. Secondly, in previous randomized controlled trials (RCTs), (combined) interventions were generally not individualized according to the subject's physical capabilities and nutritional status, despite individualization being essential to achieve maximal effects [10]. Thirdly, much of the existing research has focused on a pre-frail or frail population, rather individuals who are diagnosed with sarcopenia according to the revised criteria of the European Working Group on Sarcopenia in Older People (EWGSOP2) [1, 6–8]. Lastly, little is known about the feasibility, acceptability, and safety of implementing such a comprehensive multicomponent intervention, including a home-based exercise program, protein supplementation, and omega-3 supplementation before scaling to a definitive RCT, specifically in EWGSOP2-defined sarcopenic older adults. In contrast to previous studies, the present trial is the first randomized controlled feasibility study to investigate an individualized, multicomponent intervention (home-based resistance training, protein supplementation, and omega-3 supplementation) exclusively in an EWGSOP2-defined sarcopenic population. The primary aim was to assess the feasibility of implementing these components in this population. The secondary aim was to explore the potential efficacy of individual and combined interventions on muscle strength, mass, and physical performance in sarcopenic older adults.

2. Methods

2.1. Study overview and design

This study was a feasibility and acceptability analysis of the Exercise and Nutrition for Healthy AgeiNg (ENHANce) trial [11]. Details of the study methodology have been previously described [11]. Briefly, the ENHANce trial is a single-centre, parallel grouped, five-armed randomized assessor-blinded controlled feasibility trial with triple-blinded supplementation, aiming to assess the effect of combined anabolic interventions (protein supplementation, omega-3 supplementation and physical exercise) in community-dwelling or assisted living older adults ($\geq$65 years) during a 12-week intervention period, followed by a 12-week follow-up period. The ENHANce study was registered at ClinicalTrials.gov (NCT03649698). Ethical approval was obtained from the UZ/KU Leuven Ethical committee (s60763). The study was conducted in accordance with the Declaration of Helsinki and was reported according to the CONSORT 2010 guidelines for feasibility trials (Supplementary Material 1). All participants provided written informed consent.

2.2. Study setting

The study and its measurements took place in the University Hospitals Leuven (UZ Leuven) in Leuven, Belgium or (partly) at the participants' homes according to their ability to travel and personal preferences.

2.3. Study recruitment

Participants were recruited from various settings, and multiple recruitment initiatives were implemented throughout the recruitment period to reach as many eligible individuals as possible. Table 1 summarizes all recruitment sources used during the study, grouped by category: hospital-based, primary healthcare professionals, senior organizations, media, leaflet distribution, and other strategies.

2.4. Eligibility criteria

Participants were eligible for this study if they met the following criteria at screening: diagnosed with sarcopenia according to EWGSOP2 [10], able to communicate in Dutch, English, or French, no allergies to soy, milk, or peanut (oil), a Mini-Mental State Examination (MMSE) score of 21 or higher, no terminal illness with a prognosis of less than six months, no diseases or impairments that would hinder study participation, no acute or unstable cardiovascular issues, and no engagement in a physical training program at least twice a week in the past six months, no diagnosis of severe kidney disease (eGFR $<$ 30 ml/min/1.73m^2), fasting glycemia below 126 mg/dl, no use of anti-diabetic drugs, protein intake not exceeding 1.5 g/kg/bodyweight per day, and no cancer diagnosis or being cancer-free for more than 5 years.

2.5. Sample size

The sample size for this feasibility trial (N = 58) was determined based on practical considerations, available resources, and the completion of allocated funding, rather than formal power calculations. No a priori progression criteria were established to guide the decision on whether to proceed to a definitive trial. However, a pre-study sample size calculation was performed for a definitive trial, estimating that with a sample size of 180 participants, the RCT would have adequate power (0.80 with a two-tailed alpha level of 0.05) to detect a difference in Short Physical Performance Battery (SPPB) scores between two treatment groups. A 1 point change in SPPB score was substantially meaningful [12]. More details on this sample size calculation can be found elsewhere [11].

2.6. Randomization, allocation and blinding

Participants who met the inclusion criteria, were randomly assigned into one of five groups with the placebo group being in a 1:1 ratio by computer-generated random numbers groups: 1) Exercise (Ex) intervention alone; 2) Protein (Prot) supplementation alone; 3) Exercise intervention + protein supplementation; 4) Exercise intervention + protein supplementation + omega 3; 5) Control group (no exercise, no protein, no omega-3) (Fig. 1). Subjects were block randomized and stratified by gender using sealed envelopes to ensure allocation concealment. An independent research assistant prepared sequentially coded, sealed, and opaque envelopes containing random numbers. The random allocation sequence was exclusively accessible to the independent research assistant, ensuring blinding of participants and study personnel regarding the group assignment, except for the exercise intervention. Outcome assessments and statistical analyses were performed by assessors and statisticians who were also blinded to the study groups assignments throughout the study.

Table 1
Overview recruitment strategies in the ENHANCe trial.

Hospital	Primary healthcare professionals	Senior organisations	Media	Leaflet distributions	Other strategies
Geriatric day ward Acute geriatric wards Osteoporosis outpatient clinic Display of information clip & leaflets in several consultation wards	– General Practitioners (GPs) – Pharmacists – Home care nurses – Local physiotherapists	Local senior organisations	Information clip on regional television Local newspapers Newsletters Social media (Linkedin, UZ Leuven website)	Senior seminars Community events Service flats Day care centres Mailboxes across Leuven and nearby towns	To address transportation barriers: Taxi services Home visits
Primary recruitment source: High yield	High yield for GPs	Low yield	High yield for newspapers	High yield	
					High yield for taxi services

The table summarizes all recruitment sources used during the study, grouped by category. Notes indicate which sources were most effective.

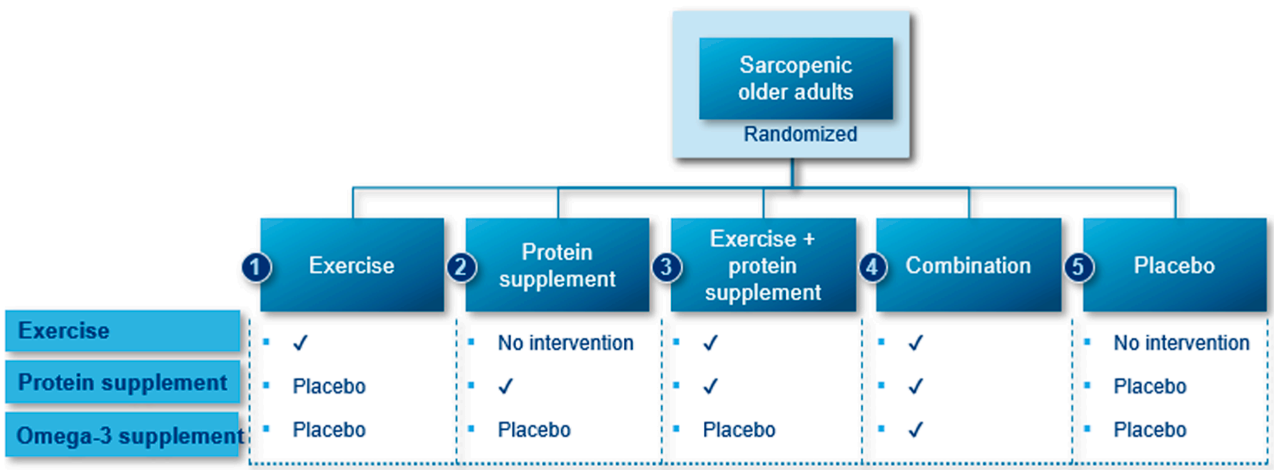

Fig. 1. Design of the ENHANCe randomized controlled trial. This five-arm trial enrolled older adults with sarcopenia who met inclusion criteria and randomly assigned them (computer-generated 1:1 allocation) to one of five groups: (1) Exercise (Ex) intervention alone; (2) Protein (Prot) supplementation alone; (3) Exercise intervention + Protein supplementation; (4) Exercise intervention + Protein supplementation + Omega 3; 5) Control group (no exercise, no protein, no omega-3).

2.7. *Intervention protocol*

2.7.1. *Standard care*

Participants in all five groups received a standard therapy of 800 international units (IU) of vitamin D3 (cholecalciferol, Vista-D3, Vista-Life) daily from four weeks before the start of the intervention, until the last day of the follow-up period.

2.7.2. *Exercise intervention*

Participants randomized in groups containing the exercise intervention (groups 1, 3 and 4) received a modified Otago Exercise Program (OEP) and a walking plan [13]. The OEP consists of warming-up, strengthening and balance training exercises and stretching, adapted to individual capabilities [13]. Exercises were performed at up to 70-80% of 1-repetition maximum (RM).

Participants were encouraged to perform the OEP three times a week and to walk two times a week during at least 30 minutes. Participants were asked to perform the OEP in close temporal proximity to one of the moments of the intake of the protein supplement. More details about the exercise intervention can be found in Supplementary Material 2.

2.7.3. *Protein intervention*

Participants in the groups containing the protein intervention (groups 2, 3 and 4) received individually adapted protein supplements to reach a total (usual diet and supplements) protein intake of ≥ 1.5 g/kg BW/day with at least 20-30 g proteins per meal as recommended by the PROT-AGE study group for older adults with sarcopenia [14]. Detailed information about the calculation of the habitual dietary protein intake and the individualized protein supplementation has been published before [15]. The participants were asked to take the protein supplement from five days before the start of the intervention until the end of the intervention period. The protein powder is commercially available and contained 4.5g protein/5g powder, composed of whey proteins with a high leucine content (9.14%) (Resource instant protein, Nestlé). Participants in the protein placebo groups (group 1 and 5) received an isocaloric identical maltodextrin placebo powder (Resource dextrin maltose, Nestlé).

2.7.4. *Omega-3 intervention*

Participants randomized in group 4 received a daily supplement with omega-3 PUFA (1 capsule providing 500 mg eicosapentaenoic acid (EPA) and 450 mg docosahexaenoic acid (DHA)) (Vista-Omega-3, Vista-Life). Participants received the supplement from four weeks before the start of the study until the end of the intervention period. Participants were instructed to take the supplement at breakfast. Groups 1, 2, 3 and 5 received identical placebo capsules containing peanut oil.

2.7.5. *Control group*

Participants randomized in group 5 (control group) received standard care (800 IU Vitamin D daily), along with the placebo equivalents of the protein powders and omega-3 capsules. Participants in this group were not prescribed any specific exercise regimen but were encouraged to maintain their usual physical activity behaviour.

2.8. Study measurements and outcomes

2.8.1. Study feasibility

The feasibility of the study was evaluated in terms of:

– Eligibility rate

= (eligible individuals/individuals assessed for eligibility) x 100

– Recruitment rate

= (individuals randomized/ individuals who were eligible) x 100

– Retention rate

= (number of participants with measurement at each timepoint/ number of participants enrolled into study) x 100

– Data completion rates for the planned outcomes (i.e. sarcopenia outcomes) in a definitive trial

= (number of data for each outcome/number of participants enrolled in the study) x 100

2.8.2. Study acceptability and safety

Study acceptability and safety were evaluated based on participants' feedback on benefits and disadvantages associated with the study, adherence to the intervention, and safety or tolerability during different time points of the study.

Participants' feedback on the benefits and disadvantages associated with the study procedures and interventions were asked by the study personnel through the following open-ended question at different timepoints of the study (W1, W4, W8, W12, W16, W20, W22, W24): *"Which benefits/disadvantage (adverse effects) related to the study procedures or intervention did you experience?"*

Adherence to the exercise intervention was assessed using a self-reported exercise diary. Participants were instructed to record when they performed the OEP and the walking program. The adherence to the protein supplement was assessed by calculation of the powder boxes returned at each visit. More specifically, empty, full or opened boxes of protein/placebo powder were counted and weighed [11].

The adherence with the omega- 3/placebo supplement was assessed by pill count of the provided and returned capsules at each visit. These adherence checks were performed at baseline (for protein and omega-3 and its placebo's), W1, W2, W4, W6, W8, W10 and W12. Adherence was calculated for the OEP sessions, the walking program, the integral exercise intervention, and the nutritional intakes (protein, omega-3). Participant' adherence to protein supplementation was calculated as the ratio of consumed protein powder to prescribed protein powder, adherence to omega-3 supplementation was calculated as the ratio of consumed pills to prescribed pills and adherence to exercise was calculated as the ratio of number of completed intervention sessions to prescribed sessions, all expressed in percentages (%).

Adherence was expressed as the mean/median and range of adherence percentages across all participants throughout the whole intervention period and per study visit.

Safety and tolerability of the trial were assessed through the reporting of adverse events, harms, or unintended side effects resulting from participation in the study, using the previously mentioned open-ended question format.

2.8.3. Potential intervention effects on sarcopenia outcomes

The following outcomes were measured at baseline, W12 and W24: SPPB, gait speed (GS), chair stand test (CST), handgrip strength (HGS), skeletal muscle mass index (SMI), and isometric, isokinetic and isotonic strength of the knee-extensor quadriceps muscles of the dominant leg.

A detailed overview of the study measurements and outcomes can be found in Supplementary Material 3 and 4.

2.9. Statistical analysis

Descriptive statistics were used to summarize feasibility, acceptability and safety data. Descriptive continuous variables were expressed as means with standard deviations (SD) or medians with interquartile range (IQR). Descriptive categorical variables were expressed as proportions (%). Baseline characteristics of the 5 groups were compared using the ANOVA (normally distributed) or Kruskal-Wallis (skewed variables) test for continuous variables and the Fisher's exact test for categorical variables. To explore the potential effect of the interventions on sarcopenia outcomes (SPPB, HGS, CST, GS, SMI, and knee extensor muscle strength (isokinetic 60°/s & 180°/s, isometric 60° & 90°, isotonic 1%)) after 12 weeks of intervention, descriptive statistics were used. Mean changes and ratios (95% CI) were reported for within-group changes, along with Cohen's D effect size. In addition to that, exploratory significance testing using linear mixed models were used to evaluate the change in sarcopenia outcomes between the treatment groups after intervention (W12). These analyses involved pairwise comparisons between treatment groups (1 vs 3, 1 vs 5, 2 vs 5, 3 vs 4) at W12. The response variables were sarcopenia outcomes with group, time point (baseline, W12), group by time interaction and gender as covariates. For right-skewed outcome variables, a log-transformation was applied to the outcome variable. In these cases, geometric means were presented and time- or group effects are presented by ratios rather than mean differences. Missing data were addressed using the linear mixed model's inherent tolerance under the Missing at Random (MAR) assumption. Parameter estimates were obtained via maximum likelihood, which provides unbiased results when missingness depends on observed outcomes or covariates. Data were analyzed according to the intention-to-treat (ITT) principle. The ITT analysis included all randomized participants (n=58), regardless of their adherence to or completion of the study protocol. To account for baseline imbalances between intervention groups, a sensitivity analysis was performed in which baseline CST, body mass index (BMI), fat mass (FM), and severe sarcopenia were added as covariates to the linear mixed models. Given the exploratory nature of the analyses, no corrections for multiplicity were performed. A significance level of 5% was used for all analyses. Analyses were performed using SAS software (version 9.4 for Windows).

3. Results

3.1. Study feasibility

3.1.1. Participants recruitment and flow

Between February 2018 and September 2024, 9731 individuals were assessed for eligibility for the ENHANce study. Of these 9731 participants, more than half (n=4940) were excluded due to specific diseases that could impose problems with study participation, such as diabetes mellitus, cancer, MMSE<21, polyneuropathy, and Parkinson's disease. A total of 1594 older adults declined participation in the interventional study for various reasons, including but not limited to lack of interest. In addition, 776 were nursing home residents, and 459 individuals did not meet the criteria for probable sarcopenia based on low muscle strength assessments using HGS and the CST. Further exclusions were due to engagement in a physical training program within the past 6 months (n = 501), transport difficulties and/or perceiving the study as too intensive (n = 208), and other reasons (n = 1253). Eventually, only 323 individuals attended a screening visit. Of these, 203 were not sarcopenic according to the EWGSOP2-criteria, 34 were excluded due to not meeting the other inclusion criteria, 28 participants declined to participate due to study intensity or a lack of interest and 58 were excluded for other reasons. Fig. 2 gives a more detailed overview on the recruitment process of the ENHANce study.

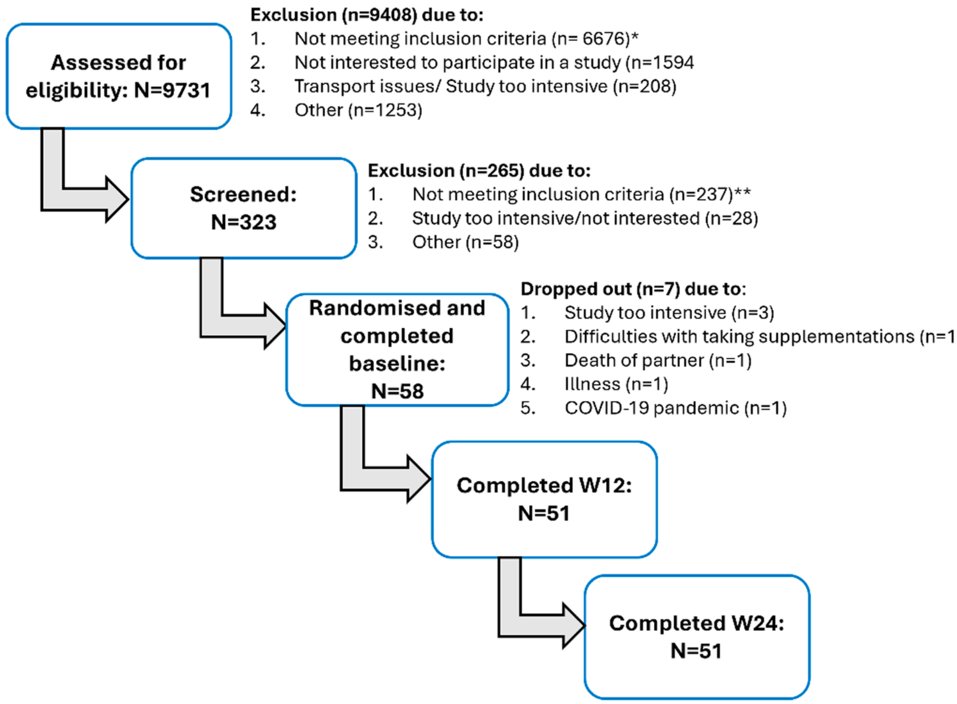

Fig. 2. Flowchart recruitment process ENHANce study. This flow diagram illustrates participant progression from initial eligibility screening to study completion. *Disease imposing hinder to participate (e.g. diabetes mellitus, polyneuropathy, cancer) (n=4940), nursing home resident (n=776), following a physical training program in the last 6 months (≥2x/week) (n=501), no sarcopenia diagnosis (n=459). **No sarcopenia diagnosis (n=203), Disease imposing hinder to participate (e.g. diabetes mellitus, polyneuropathy, cancer) (n=34)).

The eligibility rate was 29.7% (2890 eligible individuals/ 9731 individuals assessed for eligibility). Only 58 of those being eligible were finally randomized into the study, resulting in a recruitment rate of 2.0% (58 randomized participants/2890 eligible individuals). Of the 58 enrolled participants, 51 completed the 12-week intervention period and the 12-week follow-up period (87.9% retention). Nine participants were enrolled in group 1, 12 participants in group 2, 13 participants in group 3, 12 participants in group 4 and 12 participants in group 5. Seven out of 58 participants (Ex: n=1; Prot: n=2, Ex+Prot: n=2, Ex+Prot+Omega-3: n=1, Control: n=1) dropped out between baseline and week 12, and there were no drop-outs between weeks 12 and 24 (Supplementary Material 5). The main reason for drop-out was that participants perceived the study procedures and interventions as too demanding (n=3, 42.9%). The overall retention rate of the study was 87.9%.

3.1.2. Data completion rate

Data completion rate for the sarcopenia outcomes ranged from 93.1% (n=54) to 100% (n=58) at baseline. At 12 weeks and 24 weeks, the data completion rate ranged from 81.1% (n=47) to 97.9% (n=51). The quadriceps muscle strength measurements had the lowest completion rate, primarily because participants perceived the tasks on the Biodex device (approximate duration: 25-30 minutes) to be challenging and demanding (Supplementary Material 6).

3.1.3. Participant baseline characteristics

The mean age of all participants was 76.2 (±6.6) years and 65.5% of all participants were women. More than half of the participants were diagnosed with probable sarcopenia (51.7%), 41.4% had confirmed sarcopenia and 6.9% of the participants were diagnosed with severe sarcopenia. The baseline differences between the experimental groups were not statistically significant, except for BMI, FM and CST. BMI and FM were significantly higher in the Ex-only group compared with the Ex+Prot group, whereas CST performance was significantly higher in the Ex+Prot+Omega-3 group compared with both the Ex+Prot group and the Control group. A detailed overview of baseline participant characteristics for each intervention arm, along with significant between-group differences are shown in Table 2 and Supplementary Material 7.

3.2. Trial acceptability and safety

3.2.1. Participants' feedback on the study procedures and interventions

Participants reported several perceived benefits, most commonly feeling physically stronger (34.5%), more confident (20.7%), and more aware of the importance of physical activity and nutrition (22.2%). Other improvements included better balance (15.5%), walking ability (6.9%), increased energy (13.8%), and general health (13.8%). Challenges included demanding procedures (53.5%), difficulties with food diaries (22.4%), urine collection (13.8%), and discomfort from activity monitors (6.9%). Exercise-related complaints were reported by 36.2%, and protein powder issues by 29.1%, including mild gastrointestinal symptoms (10.3%). A more detailed summarizing overview can be found in Table 3.

3.2.2. Trial safety

No harms or significant adverse effects related to the study occurred during the study. The majority of the participants tolerated the interventions without any significant adverse effects. No significant negative effects were reported in the control group (Table 3).

Table 2

Baseline characteristics of participants by intervention group (N = 58). Values are presented as mean/median (SD/IQR) for continuous variables and n (%) for categorical variables. Group 1: Exercise only (n = 9), Group 2: Protein only (n = 12), Group 3: Exercise + Protein (n = 13), Group 4: Exercise + Protein + Omega-3 (n = 12), and Group 5: Control (n = 12). *Baseline differences between the groups were for: normally distributed continuous parameters assessed by ANOVA test, skewed distributed continuous parameters assessed by Kruskal-Wallis test and categorical parameters were assessed by Fisher's Exact test. Abbreviations: BMI, body mass index; FM, fat mass; PAL, Physical Activity Level; MNA, Mini Nutritional Assessment; HGS, handgrip strength; CST, chair stand test; SPPB, Short Physical Performance Battery; GS, gait speed; SMI, skeletal muscle mass index.

Variable	All N=58	Group 1: Exercise only N=9	Group 2: Protein only N=12	Group 3: Exercise+ Protein N=13	Group 4: Exercise +Protein + Omega-3 N=12	Group 5: Control N=12	p-value *
Age (years)	76.19 (6.59)	74.78 (5.47)	78.25 (5.01)	74.31 (6.59)	77.17 (8.71)	76.25 (6.61)	0.587
Female, n (%)	38 (65.5%)	7 (77.8%)	7 (58.3%)	8 (61.5%)	9 (75.0%)	7 (58.3%)	0.817
Sarcopenia status, n (%)							
• **Probable**	30 (51.7%)	8 (88.9%)	7 (58.3%)	5 (38.5%)	3 (25.0%)	7 (58.3%)	
• **Confirmed**	24 (41.4%)	1 (11.1%)	5 (41.7%)	7 (53.8%)	6 (50.0%)	5 (41.7%)	0.071
• **Severe**	4 (6.9%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	3 (25.0%)	0 (0.0%)	
BMI (kg/m^2)	26.11 (4.44)	28.53 (3.08)	28.07 (6.04)	23.92 (2.50)	23.86 (4.06)	26.98 (3.80)	**0.014**
FM (kg)	28.23 (8.95)	33.79 (7.93)	31.58 (12.07)	23.99 (4.70)	21.51 (6.10)	30.45 (7.09)	**0.006**
Daily dietary energy intake (kilocalories)	1843.49 (381.61)	2114.25 (401.83)	1906.95 (361.56)	1678.39 (284.18)	1739.67 (292.34)	1859.64 (473.58)	0.078
Steps/day	4957.10 (2327.00-8419.75)	3943.10 (2634.1-6682.08)	4394.10 (1888.5-7282.5)	4990.20 (4567.4-8674.2)	7069.10 (4272.7-8496.98)	4219.80 (2566.6-5449.25)	0.870
PAL	1.88 (0.26)	1.82 (0.13)	1.79 (0.21)	1.98 (0.31)	1.98 (0.26)	1.74 (0.23)	0.225
MNA	12.00 (10.00-14.00)	12.00 (12.00-14.00)	13.5 (11.00-14.00)	12.00 (10.00-13.00)	12.50 (10.50-14.00)	12.00 (10.50-13.50)	0.576
Vitamin D (ng/mL)	31.01 (6.47)	29.06 (5.39)	29.79 (5.39)	31.64 (8.93)	32.24 (6.74)	31.94 (6.45)	0.760
HGS (kg)							
• **Male**	27.14 (9.27)	23.88 (23.36-24.4)	30.67 (26-36.93)	26.00 (22.31-32)	23.36 (9.78-39.02)	25.00 (23.00-25.45)	0.340
• **Female**	18.67 (6.49)	25.45 (12-28.58)	20.23 (16-23.36)	19.00 (15-20.75)	16.05 (13.30-19.18)	15.00 (12.00-24.40)	
CST (s)	17.20 (15.99-21.16)	17.20 (16.80-22.32)	17.59 (15.80-21.44)	16.48 (14.45-17.35)	21.63 (19.70-27.60)	16.20 (13.90-16.77)	**0.001**
SPPB (0-12 points)	8.43 (1.86)	8.22 (2.22)	8.83 (1.75)	8.77 (1.79)	7.67 (1.82)	8.58 (1.88)	0.539
GS (m/s)	1.00 (0.88-1.15)	1.02 (0.90-1.15)	1.04 (0.91-1.32)	1.08 (1-1.14)	0.92 (0.69-1.00)	0.94 (0.86-1.10)	0.222
SMI (kg/m^2)							0.074
• **Male**	6.89 (6.16-7.69)	6.96 (6.11-7.81)	7.06 (6.27-7.79)	6.53 (6.11-6.74)	7.46 (5.48-8.98)	7.03 (6.70-7.17)	
• **Female**	5.60 (5.19-5.99)	6.05 (5.70-6.22)	5.94 (5.19-7.40)	5.64 (5.07-5.90)	5.19 (4.73-5.36)	5.58 (5.24-6.13)	
Knee extensor muscle strength							
• **Isometric 60° (Nm/kg)**							
Male	129.18 (32.05)	98.97 (16.11)	157.94 (23.67)	124.63 (32.84)	104.32 (33.92)	131.97 (24.75)	0.298
Female	92.80 (29.76)	90.46 (28.58)	71.30 (24.83)	112.74 (16.43)	90.72 (29.36)	96.21 (38.16)	
• **Isometric 90° (Nm/kg)**							
Male	159.88 (43.71)	117.06 (21.74)	208.72 (30.49)	150.31 (41.78)	145.01 (57.26)	146.68 (15.66)	0.730
Female	107.40 (41.15)	116.68 (36.43)	73.85 (20.39)	130.93 (30.41)	99.11 (52.01)	116.76 (40.10)	
• **Isokinetic 60°/s (Nm/kg)**							
Male	103.28 (31.73)	79.51 (13.36)	123.66 (33.13)	118.46 (35.79)	77.23 (25.98)	99.38 (14.96)	
Female	75.37 (27.21)	74.42 (31.43)	55.19 (17.62)	94.12 (20.84)	71.41 (27.96)	72.80 (30.57)	0.263
• **Isokinetic 180°/s (Nm/kg)**							
Male	70.21 (22.23)	44.35 (8.43)	84.07 (27.34)	81.11 (20.70)	54.16 (13.92)	67.62 (12.10)	
Female	54.32 (16.06)	57.89 (17.92)	45.66 (9.69)	62.52 (12.44)	53.92 (18.57)	51.00 (18.89)	0.390
• **Isotonic 1% (°/s)**							
Male	457.38 (108.39)	356.57 (94.39)	502.85 (96.47)	560.89 (48.58)	338.03 (80.83)	441.03 (83.10)	
Female	427.31 (129.57)	420.28 (54.58)	357.52 (81.70)	509.91 (87.20)	416.77 (191.81)	421.43 (137.87)	0.064

Values are presented as mean/median (SD/IQR) for continuous variables and n (%) for categorical variables. Group 1: Exercise only (n = 9), Group 2: Protein only (n = 12), Group 3: Exercise + Protein (n = 13), Group 4: Exercise + Protein + Omega-3 (n = 12), and Group 5: Control (n = 12).

* Baseline differences between the groups were for: normally distributed continuous parameters assessed by ANOVA test, skewed distributed continuous parameters assessed by Kruskal-Wallis test and categorical parameters were assessed by Fisher's Exact test. Abbreviations: BMI, body mass index; FM, fat mass; PAL, Physical Activity Level; MNA, Mini Nutritional Assessment; HGS, handgrip strength; CST, chair stand test; SPPB, Short Physical Performance Battery; GS, gait speed; SMI, skeletal muscle mass index.

3.2.3. *Adherence to intervention*

Mean/median adherence to the protein and placebo powders was 86.8% and 92.3%, respectively (Supplementary Material 8). Adherence values exceeding 100% may reflect instances where participants consumed more than the prescribed protein intake or minor inaccuracies occurred during home preparation, such as spillage when adding protein powder to soups or shakes. The mean/median adherence to the omega-3 capsule and placebo capsule was 95.7% and 98.2%, respectively. Median adherence to the OEP and walking program was 59.4% and 87.5% respectively, whereas the mean adherence to the integral exercise program was 70.7%. A more detailed overview of the adherence of the participants over the whole intervention period and per timepoint are

Table 3
Overview benefits and disadvantages reported by participants in response to open question. Values represent the number of participants (N) across all intervention groups and percentage (%) reporting each benefit or disadvantage during or after the 12-week intervention.

	N	%
Benefits		
Feeling ‘stronger’ in general	20	34.5%
Awareness of healthy nutrition and physical activity	13	22.4%
Specific positive experiences due to exercise program		
• Increased confidence due to exercises	12	20.7%
• Better balance due to exercises	9	15.5%
• Improved walking ability	4	6.9%
• Pain reduction due to exercises	2	3.5%
Feeling ‘healthier’ in general	8	13.8%
Increased energy and fitness	8	13.8%
Less constipation	4	6.9%
Contribution to science	3	1.7%
Social interaction	3	5.2%
Weight loss (a benefit as perceived by participants)	3	5.2%
Improved planning and organization skills	2	3.4%
Disadvantages		
Time-consuming and intensive study procedures	31	53.4%
General difficulties with exercises (e.g. too intensive, muscle stiffness, pain, general discomfort)	21	36.2%
General difficulties with protein powders (not specified)	17	29.3%
Specific difficulties with protein powders		
• Weight gain (a disadvantage as perceived by participants)	10	17.2%
• Loss of appetite	7	12.1%
• Diarrhoea	6	10.3%
• Excessive amount of protein supplementation	4	6.9%
• Constipation	4	6.9%
• Bloated feeling	4	6.9%
• Unpleasant taste of supplements	2	3.5%
• Vomiting and nausea	2	3.5%
Difficulties with food diaries	13	22.4%
Difficulties with urine collection	8	13.8%
Discomfort with wearing physical activity monitor	4	6.9%

shown in Supplementary Material 8 and 9.

3.3. Potential effect of the 12-weeks intervention

The Exercise-only group showed a significant 23% improvement in CST (ES: -1.18), but no other sarcopenia outcomes changed significantly after 12 weeks. The Protein-only group showed no significant changes from baseline. The Exercise+Protein group improved significantly in SPPB (+1.13 points, ES: 0.79) and CST (-20% time, ES: -0.94). The Exercise+Protein+Omega-3 group showed significant improvements in SPPB (+1.19 points, ES: 1.04), CST (-31% time, ES: -0.56), and quadriceps strength across all measures (Supplementary Material 10 and 11).

The Placebo group showed no significant changes.

Pairwise comparisons revealed significantly greater improvements in SMI and quadriceps strength in the Exercise+Protein+Omega-3 group compared to Exercise+Protein, suggesting a synergistic effect of the triple intervention (Supplementary Material 10 and 11). However, this group also showed notable baseline imbalances in CST, BMI, FM, and a higher prevalence of severe sarcopenia compared to the other groups. Sensitivity analyses adjusting for these baseline variables showed similar results, with the intervention effects remaining statistically significant. These findings indicates that the observed improvements are not explained by the baseline differences (Supplementary Material 12).

4. Discussion

In this study, we aimed to evaluate the feasibility and acceptability of a 5-armed RCT using a multicomponent intervention in community-dwelling older adults with sarcopenia according to the EWGSOP2 definition. Additionally, we explored the potential efficacy of these (combined) anabolic interventions on sarcopenia outcomes in a sample of 58 ENHANce participants.

4.1. Trial feasibility

The ENHANce study encountered substantial recruitment challenges, achieving only 29.7% eligibility and a 2.0% recruitment rate, which made the original target of 180 participants unattainable. Several barriers contributed to this outcome. First, engaging sarcopenic older adults in a demanding 7-month trial with extensive study procedures and three intervention types proved difficult. Second, disruptions caused by COVID-19 restrictions during 2020–2021 further hindered participation. Finally, stringent inclusion criteria excluded more than half of screened individuals, primarily due to comorbidities such as diabetes, Parkinson’s disease, cancer, or cognitive impairment. Despite these recruitment difficulties, retention and data completion at 12 and 24 weeks were high, indicating strong adherence once enrolled. These findings suggest that the main challenge lies in initial recruitment rather than study adherence, a challenge well-documented in the literature [16,17]. The most effective recruitment strategies involved direct engagement in geriatric day wards and osteoporosis clinics, GP referrals, advertisements in newsletters and logistical support such as taxi services. These findings suggest that future large-scale RCTs should adopt multicenter designs, broader inclusion criteria, and active healthcare provider involvement to enhance reach.

4.2. Trial acceptability and safety

Participants reported numerous perceived benefits, including improvements in physical strength, confidence, balance, energy levels, and increased awareness of healthy nutrition and physical activity. Conversely, more than half of the participants reported that the study procedures and interventions were too time-consuming and demanding. Adherence to the interventions showed high variability between individuals and fluctuations at different time points, especially for protein supplementation. This might be explained by concerns about weight gain, appetite loss, and gastrointestinal symptoms. These adherence challenges are well-documented in the literature, which highlights factors such as taste, texture, and gastrointestinal intolerance as being associated with lack of adequate protein intake in an older population. Enhancing supplement flavor or guiding dietary protein intake may improve adherence [18,19]. Interestingly, some participants appeared to have adherence rates exceeding 100% for protein supplementation, which may suggest overconsumption or spillage during measurement. This highlights a potential limitation of using weighed protein powders to assess adherence and should be considered when interpreting these results. Adherence to the walking program was high (87.5%), while OEP adherence was moderate (59.4%), likely due to its structured nature. Group-based exercise programs, or including some group sessions in addition to the home-based program may improve adherence and attendance rates among older adults [20,21].

4.3. Potential effects of the (combined) interventions on the sarcopenia outcomes

Exploratory findings suggest that the Exercise-only group improved CST, the Exercise+Protein group improved SPPB and CST, and the Exercise+Protein+Omega-3 group showed gains in SPPB, CST, and quadriceps strength after 12 weeks. These findings are exploratory and limited by the study’s small sample size. The modified OEP improved CST but had limited impact on other outcomes, likely due to its main focus on lower limb strength.

Protein supplementation alone did not significantly improve outcomes, possibly due to mild baseline energy deficits and inconsistent adherence, which may have reduced its anabolic potential [22]. Also, the non-significant improvements in the placebo group suggest a possible Hawthorne effect, where participants may have unconsciously increased activity or protein intake [23–25].

The Exercise+Protein group showed a 1.13-point improvement in SPPB, which is a clinically meaningful improvement (≥1 point). However, this improvement was not significantly greater than that observed in the Exercise-only group (0.61 points), suggesting that protein supplementation provides limited additional benefit. Adherence variability and low statistical power may have influenced these results. Given mixed findings in prior studies, further long-term research is needed to clarify the impact of these combined interventions on muscle function in older adults with sarcopenia [6,8].

Adding omega-3 PUFAs supplementation to the Exercise+Protein group demonstrated significant improvements in SPPB, CST, and quadriceps strength. Omega-3 PUFAs may theoretically enhance the anabolic response to protein and exercise, reduce age-related chronic low-grade inflammation, improve mitochondrial function and insulin sensitivity, and thereby support muscle protein synthesis and counteract mechanisms underlying sarcopenia [9]. Importantly, this group presented with more severe sarcopenia and lower BMI/FM at baseline compared to other groups, which may have provided greater potential for improvement. This raises the possibility that the observed changes could reflect regression to the mean rather than a true synergistic effect of omega-3 supplementation. Nevertheless, our sensitivity analyses, adjusting for baseline CST, FM, BMI, and severe sarcopenia, showed that the intervention effects remained significant, suggesting that these improvements cannot be fully attributed to baseline differences. However, due to the small sample size, our findings should be interpreted with caution and no definitive conclusions regarding synergy can be fully drawn from this feasibility study.

4.4. Strengths and limitations

A first major strength of the ENHANce study is that it provided novel and valuable insights into the significant recruitment challenges in the field of sarcopenia, participants' experiences, and the adherence behaviour of sarcopenic older adults participating in a multifaceted interventional trial. This study informs future sarcopenia research and underscores the need for targeted engagement strategies and manageable intervention designs for older adults. Another strength is the exploration of omega-3's additive effect alongside exercise and protein supplementation, an area previously underexplored in EWGSOP2-defined sarcopenia. Thirdly, interventions were optimized and individualized based on baseline capabilities and intake, and included placebo controls for both supplements. Lastly, adherence was closely monitored through biweekly visits, enhancing intervention efficacy.

A major limitation of this study is its small sample size, which reduced statistical power and led to unequal group sizes, affecting detection of significant differences. Secondly, the low number of men, baseline imbalance between groups in differences in body composition and unequal distribution of severe sarcopenia might have influenced the results [26]. In addition, confounders such as seasonal variation in vitamin D and dietary intake might have slightly influenced the outcomes. Thirdly, complete blinding was not possible for the exercise component, potentially affecting participant behavior. Fourthly, methods used to measure adherence to the interventions were subjective and prone to self-reporting bias or measurement imprecision. Lastly, population bias, predominantly Caucasian participants from a single center, limits generalizability of our findings. Moreover, it is important to note that our study participants were likely more motivated and health-conscious than the general older adult population, which may limit the generalizability of our findings (health-conscious recruitment bias). Future studies should aim for more diverse recruitment across gender, ethnicity, and socioeconomic backgrounds, particularly among less engaged older populations.

4.5. Implications for future RCT designs targeting sarcopenia

Overall, the ENHANce trial revealed several important feasibility challenges that must be addressed before scaling to a definitive randomized controlled trial. Recruitment showed to be particularly difficult, highlighting the need for more targeted strategies, including stronger involvement of patients and general practitioners, public outreach through newsletters and newspapers, and multicenter collaboration. The high perceived study burden further limited participation, as many eligible individuals declined due to intensive procedures and frequent hospital visits. Future studies should therefore simplify protocols, reduce administrative and assessment burden, and expand the use of home-based assessments and transportation support. Variability in adherence across participants also emerged as a major challenge. This underscores the importance of tailored and continuous motivational support, regular feedback, and patient education. Adherence to exercise may be enhanced through tele-supervised or group-based training programs. Nutritional adherence could be improved by optimizing the taste of the supplements and offering practical strategies to incorporate protein-rich foods into daily meals (see Table 4).

Table 4
Lessons learned from the ENHANce trial and implications for future research.

Challenges of the ENHANce trial	Lessons learned	Recommendations for future research
1. Low recruitment success: Reaching, identifying, and motivating sarcopenic older adults to participate in an interventional study proved to be challenging.	Develop more targeted recruitment strategies	– Involve general practitioners for referrals to leverage trusted relationships. – Utilize public outreach via newspapers and newsletters. – Collaborate across multiple centres to increase sample size and representativeness.
2. High study burden: Many eligible participants chose not to participate because the study procedures were too intensive.	Reduce participant burden	– Simplify study protocol and reduce assessment burden (e.g. less frequent hospital visits, less administrative burden). – Consider at-home visits or offer taxi services to resolve transportation issues.
3. Inconsistent adherence to the interventions The adherence of ENHANce participants was inconsistent, with significant variability observed between individuals.	Improve adherence to the interventions	– Offer tailored support, including continuous motivation and encouragement: regular feedback. – Highlight the benefits through patient education. – *Exercise*: Tele-supervised exercise sessions, community-based delivery if group training is preferred (e.g. in community centres or local gyms). – *Nutrition*: Optimize supplement flavor or provide practical tips for incorporating protein-rich foods into daily meals rather than using supplements. – Use objective tools to monitor and encourage adherence.
4. Low participant diversity	Recruit across diverse locations	– Recruit a more diverse cohort: include individuals from different ethnic and socio-economic background.

Summarizing overview of challenges associated with ENHANce trial, lessons learned and implications for future research.

5. Conclusion

This feasibility trial provides essential groundwork for developing future multicomponent interventions targeting sarcopenia. More specifically, the study demonstrated that implementing a five-arm RCT in older adults was feasible in terms of safety but challenged by low recruitment, high study burden, and moderate acceptability. Preliminary efficacy results showed that exercise combined with individualized protein supplementation may have potential to significantly increase physical function, however this approach seemed to not be superior to exercise only. Moreover, incorporating omega-3 PUFAs may provide further benefits for muscle strength and mass. However, these findings in our small sample size remain exploratory and urge further confirmation in larger interventional studies. Crucially, this study emphasizes the need for multi-site recruitment, simplified protocols, and tailored engagement strategies in future definitive trials. These insights will guide the development of larger, more pragmatic studies aimed at improving outcomes for older adults at risk of sarcopenia.

Data availability

All data are available upon reasonable request from the corresponding author.

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Generative AI and figures, images and artwork

The authors declare that no generative artificial intelligence (AI) tools were used in the writing of this manuscript, nor in the creation of figures, images, or artwork.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Evelien Gielen reports financial support was provided by Research Foundation Flanders (FWO). Jolan Dupont reports financial support was provided by Research Foundation Flanders (FWO). Evelien Gielen reports financial support was provided by Nestle. Evelien Gielen reports financial support was provided by Vista-Life. Evelien Gielen reports a relationship with UCB that includes: speaking and lecture fees and travel reimbursement. Jolan Dupont reports a relationship with UCB that includes: speaking and lecture fees and travel reimbursement. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

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