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Blended home-based exercise and dietary protein in community-dwelling older adults: a cluster randomized controlled trial

Jantine van den Helder MSc.[1,2]*, Sumit Mehra MSc.[4,5,6], Carliene van Dronkelaar MSc.[1], Gerben ter Riet MD PhD[1,2,7], Michael Tieland PhD[1], Bart Visser PhD[2,3], Prof. Ben J.A. Kröse PhD[4,6], Prof. Raoul H.H. Engelbert PhD[2,3,8] & Prof. Peter J.M. Weijs PhD[1,10,3,9]

[1]*Center of Expertise Urban Vitality, Faculty of Sports and Nutrition (room B1.28), Amsterdam University of Applied Sciences, Amsterdam, The Netherlands,* [2]*Center of Expertise Urban Vitality, Faculty of Health, Amsterdam University of Applied Sciences, Amsterdam, The Netherlands,* [3]*Amsterdam Movement Sciences, Amsterdam University Medical Centers, VU University, Amsterdam, The Netherlands,* [4]*CREATE-IT Applied Research, Faculty of Digital Media and Creative Industries, Amsterdam University of Applied Sciences, Amsterdam, The Netherlands,* [5]*Applied Psychology, Faculty of Applied Social Sciences and Law, Amsterdam University of Applied Sciences, Amsterdam, The Netherlands,* [6]*Informatics Institute, University of Amsterdam, Amsterdam, The Netherlands,* [7]*Department of Cardiology, Amsterdam University Medical Centers, University of Amsterdam, Amsterdam, The Netherlands,* [8]*Department of Rehabilitation, Amsterdam University Medical Centers, University of Amsterdam, Amsterdam, The Netherlands,* [9]*Department of Nutrition and Dietetics, Amsterdam University Medical Centers, VU University, Amsterdam, The Netherlands,* [10]*Amsterdam Public Health Research Institute, Amsterdam University Medical Centers, VU University, Amsterdam, The Netherlands*

Abstract

Background Effective and sustainable interventions are needed to counteract the decline in physical function and sarcopenia in the growing aging population. The aim of this study was to determine the 6 and 12 month effectiveness of blended (e-health + coaching) home-based exercise and a dietary protein intervention on physical performance in community-dwelling older adults.

Methods This cluster randomized controlled trial allocated 45 clusters of older adults already engaged in a weekly community-based exercise programme. The clusters were randomized to three groups with ratio of 16:15:14; (i) no intervention, control (CON); (ii) blended home-based exercise intervention (HBex); and (iii) HBex with dietary protein counselling (HBex-Pro). Both interventions used a tablet PC with app and personalized coaching and were targeting on behaviour change. The study comprised coached 6 month interventions with a 6 month follow-up. The primary outcome physical performance was assessed by modified Physical Performance Test (m-PPT). Secondary outcomes were gait speed, physical activity level (PAL), handgrip muscle strength, protein intake, skeletal muscle mass, health status, and executive functioning. Linear mixed models of repeated measured were used to assess intervention effects at 6 and 12 months.

Results The population included 245 older adults (mean age 72 ± 6.5 (SD) years), 71% female, and 54% co-morbidities observed. Dropout of the intervention was 18% at 6 months and 26% at 12 months. Participants were well functioning, based on an m-PPT score of 33.9 (2.8) out of 36. For the primary outcome m-PPT, no significant intervention effects (HBex, +0.03, $P = 0.933$; HBex-Pro, −0.13, $P = 0.730$) were found. Gait speed (+0.20 m/s, $P = 0.001$), PAL (+0.06, $P = 0.008$), muscle strength (+2.32 kg, $P = 0.001$), protein intake (+0.32 g/kg/day, $P < 0.001$), and muscle mass (+0.33 kg, $P = 0.017$) improved significantly in the HBex-Pro group compared with control group after 6 month intervention. The protein intake, muscle mass, and strength remained significantly improved after 12 months as compared with those of control. Health change and executive functioning improved significantly in both intervention groups after 6 months.

Conclusions This HBex and dietary protein interventions did not change the physical performance (m-PPT) in community-dwelling older adults. Changes were observed in gait speed, PAL, muscle mass, strength, and dietary protein intake, in response to this combined intervention.

Keywords Aging; Behaviour change; e-Health; Physical functioning; Protein; Sarcopenia

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*Correspondence to: Jantine van den Helder, Faculty of Sports and Nutrition, Center of Expertise Urban Vitality, Amsterdam University of Applied Sciences, Dokter Meurerlaan 8, 1067 M, Amsterdam, The Netherlands. Tel: +31621155919. Email: j.e.m.van.den.helder@hva.nl

Introduction

The share of the aging population will rise in the upcoming decades,[1] with advancing age older adults experiencing an increase in physical limitations. These limitations are mainly caused by sarcopenic characteristics, such as a decrease in muscle mass, muscle strength, and physical performance.[2] Subsequently, this decline in physical performance is associated with increased prevalence of chronic conditions and falls, diminished physical activity, autonomy, and quality of life.[3–5]

Exercise training and nutritional interventions have shown to be effective strategies to counteract declines in muscle mass, muscle strength, and physical performance.[6,7] However, once-weekly exercise programmes in community settings have shown to be ineffective in the preservation of physical performance.[8] Also, motivation is challenged owing to the cost, time, and effort.[9]

Home-based exercise training has been shown to improve physical performance, physical activity, balance, mobility, and strength in older adults.[10,11] e-Health combined with personalized coaching, a blended approach, may result in higher motivation and adherence to home-based exercise training.[12] Previous research showed that e-health may be effective in improving muscle mass, physical performance,[13] and physical activity,[14] although the number of studies including home-based exercise training with e-health is limited.[15,16]

To further improve the effects of exercise training on muscle mass and physical performance, adequate dietary protein intake has been suggested.[17–19] No well-designed studies are available of the impact of protein counselling during home-based exercise training programmes with additional e-health on muscle mass and physical performance in community-dwelling older adults.

The VITAMIN (VITal AMsterdam older adults IN the city) research group therefore developed a new intervention: a blended home-based exercise programme, including e-health and personalized coaching, with or without a dietary protein counselling intervention.[20,21] The aim of this study is to evaluate the 6 and 12 month effectiveness of this blended home-based exercise training programme as well as the additional value of increased dietary protein on physical performance in community-dwelling older adults.

Materials and methods

Study design

The study consisted of a cluster randomized controlled trial (RCT). Clusters of community-dwelling older adults engaged in a weekly community-based exercise programme were randomly allocated to three groups:

1 no intervention (control group: CON),
2 blended home-based exercise intervention (HBex), and
3 HBex combined with a dietary protein counselling intervention (HBex-Pro).

The intervention period with personalized coaching was 6 months. The intervention continued from 6 up to 12 months without the personalized coaching, resulting in a 12 month follow-up evaluation. For assessment of the intervention effect and follow-up effect, we collected data at screening, the post-randomization baseline visit, 6 month effect visit (end of coaching), and 12 month follow-up (end of study) at the Amsterdam Nutritional Assessment Center. The study was approved by the Medical Ethics Committee (METC) of the Amsterdam University Medical Centers, location VUmc, The Netherlands (protocol ID: 2016.025), and registered at The Netherlands National Trial Register https://www.trialregister.nl/trial/5472 (NTR) NL5472/NTR5888.

Participants

We recruited participants from the Amsterdam metropolitan area, The Netherlands, between March 2016 and June 2017. Older adults were recruited through local community-based centres offering weekly exercise programmes and through a postal mailing that addressed 10 000 community-dwelling inhabitants of the Amsterdam region. Applicants were included if they met the following criteria: (i) 55 years of age or older, (ii) willingness of the general practitioner to be notified on study participation, (iii) willingness to comply with the protocol in the opinion of the study physician, (iv) ability to understand the Dutch language, (v) absence of current alcohol or drug abuse in the opinion of the investigator, (vi) absence of cognitive impairment, indicated by a score of 15 or less on the Mini-Mental State Examination, and (vii) absence of knee or hip surgery in the last 6 months. The protocol that details the study has been published, including detailed methods, inclusion criteria, measurement procedures, and interventions.[21]

Randomization

Eligible older adults were participating in weekly community-based exercise programmes, whereas these groups were defined as clusters to be randomized. After an informed consent was obtained of all individual participants of a cluster, this cluster was randomized by the unblinded study assistant (CvD.) according to the computer-generated randomization lists created by a statistician without a role in the study (MS). By necessity, participants and junior professionals, those assessing the participants and those delivering the interventions, were not blind to allocation.

Interventions

Control group

Participants in the control group followed their weekly community-based exercise programme and were asked to continue their regular lifestyle.

Blended home-based exercise training

Participants in both intervention groups (HBex and HBex-Pro) received in addition to their weekly exercise an HBex program. This included a tablet PC with developed app and personalized coaching. The app allowed participants to draw up a personalized weekly programme with progressive functional training exercises (type, level, duration, sets, and complexity). Further details are presented elsewhere,[20–22] and an overview of the functional training programme is available at *Data S1*. A junior exercise coach was assigned to each participant, who received extensive training in the topics of functional training and coaching. During face-to-face visits or tablet-supported video calls, the coaching included techniques related to self-regulation and competence. The coaching was operationalized according to the coach manual. The coaching period comprised weekly contact in the first 2 months, fortnightly in the next 2 months, and once a month in the final 2 months.

Dietary protein counselling

Participants in the HBex-Pro group received personalized dietary counselling to optimize their protein intake. This counselling was conducted by junior dietitians and focused on increasing protein intakes to a minimum of 1.2 g/kg/day and optimum of 1.5 g/kg/day,[17] timing (breakfast, lunch, dinner, and snacks), and source of protein (high-quality protein sources, such as dairy protein). Moreover, the coaching was operationalized in accordance with the exercise coach, included similar coach techniques (e.g. motivational interviewing), and was operationalized according the coach manual. A coaching schedule is available at *Data S2*.

Outcomes

Baseline demographic information was collected; medical history and current status on diagnoses, disabilities, treatments, and medications were reported.

Physical functioning

The primary outcome is measured with the modified Physical Performance Test (m-PPT). The m-PPT was performed as an assessment of multiple dimensions of physical functioning [basic and complex activities of daily living (ADL)] and consists of nine items[23]: (i) progressive Romberg test (0–4 points); (ii) chair rise (0–4 points); (iii) book lift (0–4 points); (iv) put on and take off a coat (0–4 points); (v) pick up a coin (0–4 points); (vi) 15.2 m walk (0–4 points); (vii) turn 360° (0–4 points); (viii) one flight of stairs (0–4 points); and (ix) four flights of stairs (0–4 points). All items of the test compose a maximum score of 36 points. The m-PPT and upcoming physical functioning tests have proven clinometric qualities in research for older adults.[24–26]

The secondary outcomes were the short physical performance battery (SPPB), timed-up-and-go test (TUG), 6 min walk test (6MWT), physical activity level (PAL), and handgrip muscle strength (HGS). The SPPB and TUG are commonly used to assess lower extremity functioning in a frail elderly population, and the 6MWT is also valid to assess performance-based endurance in healthy older adults.[24] As physical functioning includes physical activity, PAL was estimated with a 3 day self-report record.[27] HGS was assessed with a hand dynamometer (Jamar, USA) and used as parameter of muscle functioning.[24] Every hand was alternately assessed three times; for analysis, the average of the dominant hand was used.

Nutrition and body composition

Dietary protein and energy intake was derived from a 3 day food record,[28] with use of NEVO-codes version 2013. Skeletal muscle mass (SMM) was assessed with a whole-body dual-energy X-ray absorptiometry scan (DXA, Hologic Discovery, The Netherlands) in order to predict SMM in arms and legs. Two trained assessors (C v D. and J S) analysed the scans with the Hologic software package, and a third independent lab coordinator reviewed the analysing procedures.

Health status

Health-related quality of life was measured with the RAND-36 questionnaire. The Dutch translation of the 36-Item Short-Form Health Survey (SF-36v2) was used.[29] Health-related and self-reported summary component scores physical and social functioning were derived, accompanied with the seven subsequent component scores. Besides, the 30-item geriatric depression scale (GDS) was used to identify depression in older adults.[30]

Executive functioning

Changes in executive functioning were measured with the trail-making test (TMT), the Stroop Color–Word test (SCW), and the letter-fluency test (LF).[31]

Adherence rates

Self-reported average adherence per week was computed for Weeks 1 to 26 for the following outcomes: the number of exercises and the number of days of exercise per week. Participants were defined as adherent to the exercise guidelines when the exercise programme was used ≥2 days per week. Participants were defined as adherent to the dietary counselling if they reported average ingestion of at least 80% of the recommended protein intake of 1.5 g/kg/day, derived from the self-reported 3 day food record after 6 months.[21]

Data collection and statistical analysis

The sample size was based on the primary outcome. To detect a statistically significant difference in m-PPT after 6 months between the groups with an 80% statistical power and a significance level of 0.05, a sample size of 56 for each of three arms was estimated. Assuming a 40% dropout, a total number of 80 participants per group was indicated, resulting in 240 participants in the study.[21,26]

We used an intention-to-treat analytic strategy, including all participants who were able to visit the study location. For primary analyses, we used a linear mixed model (LMM) of repeated measures with a three-level structure in order to adjust for the extra level of cluster and account for missing values in a clinical trial setting. Time and time * group interaction were defined as fixed factors; subject and cluster were included as random intercepts; and if indicated, time was added as random slope.[32] Changes in m-PPT and secondary outcomes were visualized over the entire time course using the estimated marginal means. Intervention effects were reported as difference with 95% confidence interval and *P*-values. Additional per-protocol analysis included the exercise adherend participants only. Detailed analyses were stated in the Statistical Analysis Plan, which was finalized before unblinding of the study. Statistical analyses were performed using SPSS Statistics v24.0 (IBM, USA) and the LMM with STATA/SE v13.0 (StataCorp LLC, USA). An α of 0.05 was used to determine statistical significance.

Results

In total, 95% of the screened community-dwelling older adults were eligible and were randomized. This resulted in 45 (median [inter-quartile range], 4 [3–7]; ratio 16:15:14) randomized clusters with a total of 245 participants. Most exclusions were due to co-morbidities and related disability to comply to the protocol. During the intervention period of 6 months, the total dropout was 18%: 11% (n = 10) for CON, 14% (n = 9) for HBex, and 31% (n = 21) for HBex-Pro. Part of the total dropout was medical dropout (CON, n = 5; HBex, n = 1; and HBex-Pro, n = 6). Five serious adverse events (SAEs) were reported during the intervention period and two SAEs during the follow-up, but without relation to the study. In total, 224 older adults completed the baseline visit, 184 older adults completed the 6 month effect visit (CON, n = 81; HBex, n = 56; and HBex-Pro, n = 47), and 166 older adults completed the 12 month follow-up visit (CON, n = 77; HBex, n = 46; and HBex-Pro, n = 43) (*Figure* 1).

Clinical characteristics

Clusters were randomized over three groups before baseline (*Table* 1). At baseline, participants had a mean (SD) age of 72.0 (6.5) years and a body mass index of 26.0 (4.2), and 71% were female. Overall, the participants were well functioning, based on an m-PPT score of 33.9 (2.8) out of a maximum of 36. Most common medical conditions were musculoskeletal disorders (58%) and cardiovascular diseases (54%). Co-morbidity of two or more medical conditions was observed in 54%. Six per cent of the population was characterized as probable sarcopenic and 1% as confirmed sarcopenic.[2]

Effectiveness

Physical functioning

No significant intervention effects were found for the m-PPT (HBex, +0.03; P = 0.933; HBex-Pro, −0.13; P = 0.730) or follow-up effects. Similar absence of significant effects was found for the secondary physical performance outcomes SPPB, 6MWT, and TUG. However, significant intervention effects were observed for gait speed (+0.20; P = 0.001) as well as PAL (+0.06; P = 0.008) in HBex-Pro at 6 months compared with CON. These two effects were not sustained at 12 month follow-up (*Table* 2 and *Figure* 2A–C). Also, for HGS, a significant 6 and 12 month effect was found for HBex-Pro (+2.32; P = 0.001|+1.52; P = 0.032) (*Table* 2 and *Figure* 2D).

Nutrition and body composition

Table 2 and *Figure* 2E show that the HBex-Pro group was able to significantly increase their daily protein intake with regular food products than the other two groups. The mean intake increased in 6 months from 1.05 (0.0) to 1.41 (0.0) g/kg/day and was partly sustained at 1.24 (0.0) g/kg/day at 12 months. This resulted in a significant 6 and 12 month effect on protein intake in HBex-Pro (+0.32; $P < 0.001$|+0.23; $P < 0.001$). The SMM decreased over time in CON ($\Delta - 0.3$ kg), decreased to less extent in HBex ($\Delta - 0.2$ kg), and was preserved in HBex-Pro (Δ 0.0 kg) at 6 months (*Table* 2 and *Figure* 2F). A significant 6 and 12 month effect on SMM was observed for HBex-Pro (+0.33; P = 0.017|+0.51; $P < 0.001$).

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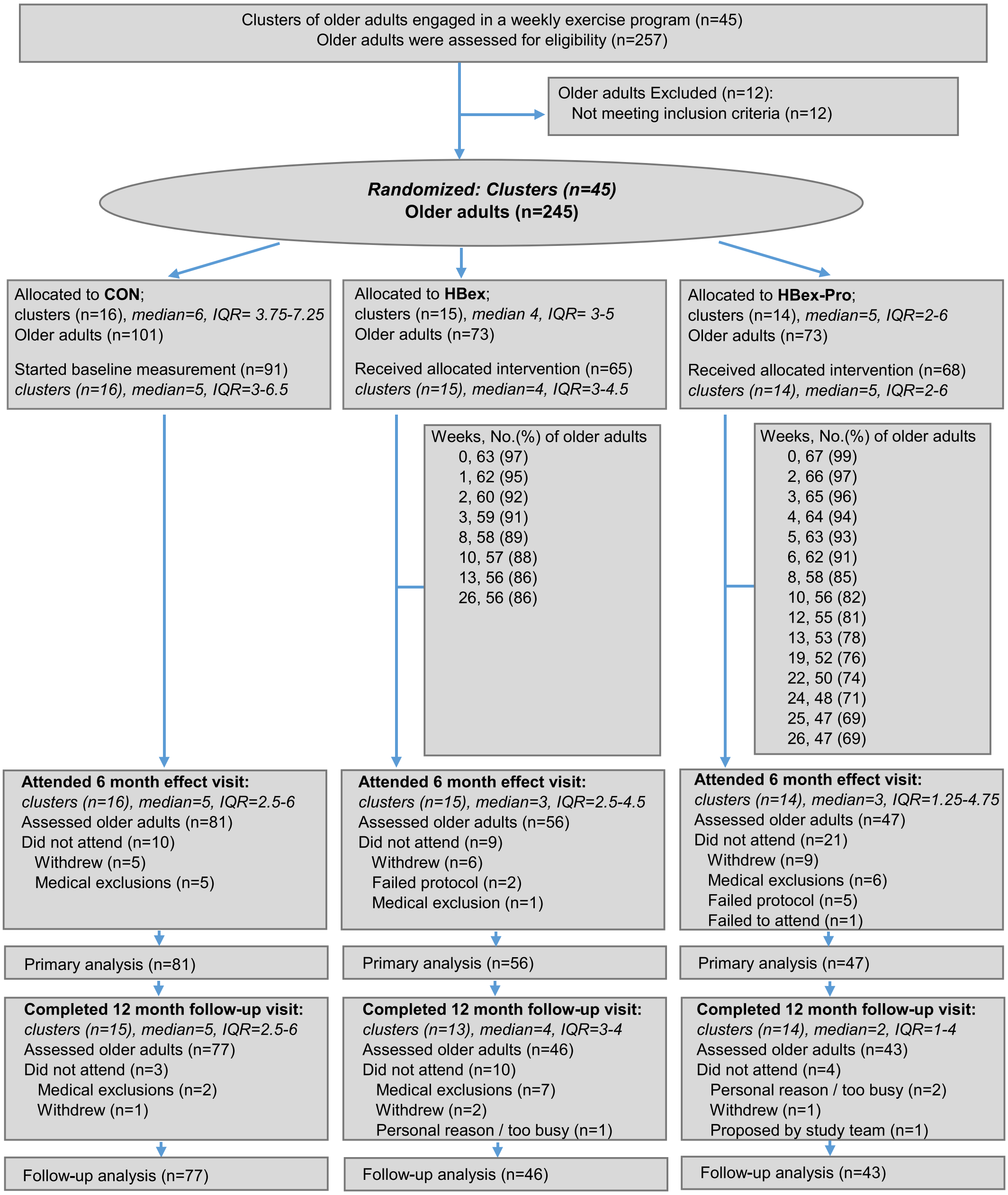

Figure 1 CONSORT flow diagram of VITAMIN study clusters and participants. CON, no intervention, control; HBex, blended home-based exercise intervention; HBex-Pro, HBex with dietary protein counselling; IQR, inter-quartile range.

Health status

There were no significant intervention effects for the RAND-36 physical and social functioning scores. However, there was a relevant significant increased health change score at 6 months for HBex-Pro (+6.93; P = 0.011) and a trend for an increased health change score for HBex (+4.73; P = 0.066). There were no significant effects reported for GDS (*Table* 2).

Executive functioning

No significant intervention effects were found for the TMT Part A and Part B. Intervention effects were observed for SCW. Part I revealed intervention effects for HBex (−2.06; P = 0.012) and HBex-Pro (−2.85; P = 0.001) with both an additional follow-up effect. Part II also revealed an intervention effect for HBex (−2.38; P = 0.010), a trend for HBex-Pro (−1.66; P = 0.087), and a trend for follow-up effect for HBex

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Table 1 Baseline characteristics of the participants

Characteristics[a]		Total (n = 224)	CON (n = 91)	HBex (n = 65)	HBex-Pro (n = 68)
Age, years		72.0 (6.5)	72.8 (6.5)	72.3 (5.8)	70.8 (6.8)
Female sex, *n* (%)		158 (71)	66 (73)	43 (72)	49 (72)
Level of education,[b] *n* (%)	Low education	99 (44)	41 (45)	28 (43)	30 (44)
Ethnicity, *n* (%)	Caucasian	213 (96)	88 (97)	61 (94)	64 (94)
MMSE, score		28.3 (2.0)	28.3 (1.7)	28.6 (1.7)	27.9 (2.6)
Sarcopenia,[c] *n* (%)	No sarcopenia	208 (93)	86 (94)	61 (94)	61 (90)
	Probable	14 (6)	4 (4)	4 (6)	6 (9)
	Confirmed	2 (1)	1 (1)	0 (0)	1 (2)
Frailty score,[d] *n* (%)	Non-frail	194 (87)	78 (86)	60 (92)	56 (82)
	Mildly frail	27 (12)	13 (14)	3 (5)	11 (16)
	Moderately frail/frail	3 (1)	0 (0)	2 (3)	1 (1)
Medical conditions,[e] *n* (%)	Musculoskeletal	130 (58)	53 (58)	40 (61)	37 (54)
	Arthrosis	52 (23)	19 (21)	15 (23)	18 (27)
	Cardiovascular	120 (54)	52 (57)	34 (52)	34 (50)
	Orthopaedic implants	28 (13)	8 (9)	13 (20)	7 (10)
	Respiratory	22 (10)	6 (6)	9 (14)	7 (10)
	Diabetes type II	14 (6)	3 (3)	6 (9)	5 (7)
	Co-morbidity (≥2 diseases)	121 (54)	50 (55)	36 (55)	36 (53)
Physical functioning					
m-PPT, score		33.9 (2.8)	34.0 (2.5)	33.9 (3.1)	33.9 (2.8)
TUG, s		7.45 (2.0)	7.43 (1.6)	7.34 (2.6)	7.59 (1.8)
SPPB, score		11.29 (1.2)	11.26 (1.3)	11.42 (1.1)	11.19 (1.2)
6MWT, m		508 (91)	517 (90)	511 (93)	490 (91)
Physical activity level, PAL (avMETs/day)		1.50 (0.15)	1.52 (0.15)	1.50 (0.15)	1.48 (0.13)
HGS, kg		29.5 (10.8)	30.0 (11.8)	30.0 (9.3)	28.3 (10.9)
Nutrition and body composition					
BMI, kg/m^2		26.0 (4.2)	25.7 (3.7)	25.3 (3.8)	27.0 (5.0)
BMI cat	Underweight	2 (1)	1 (1)	1 (2)	0 (0)
	Normal weight	104 (46)	40 (44)	35 (54)	29 (43)
	Overweight	86 (38)	41 (45)	22 (34)	23 (34)
	Obese	32 (14)	9 (10)	7 (11)	16 (24)
Skeletal muscle mass, SMM, kg		20.8 (4.7)	20.6 (4.5)	21.0 (5.3)	20.8 (4.2)
Fat mass, %		32.2 (6.5)	32.0 (6.3)	31.1 (6.2)	33.6 (6.9)
Energy intake, kcal/day		1880 (472)	1897 (451)	1817 (433)	1918 (533)
Protein intake, g/kg/day		1.08 (0.29)	1.09 (0.26)	1.06 (0.30)	1.07 (0.31)
Health status					
RAND-36 health survey scores	Physical functioning	83.8 (17.4)	83.3 (17.3)	85.5 (18.2)	82.8 (16.9)
	Social functioning	88.0 (17.0)	88.6 (17.3)	89.2 (16.2)	86.0 (17.5)
	Role of disability (PP)	78.0 (23.3)	78.0 (23.8)	80.7 (23.2)	75.5 (22.9)
	Role of disability (EP)	85.2 (18.7)	88.2 (16.8)	84.4 (19.0)	82.2 (20.5)
	Mental functioning	79.9 (13.7)	82.0 (14.4)	80.2 (13.8)	76.8 (12.2)
	Vitality	71.4 (15.0)	72.9 (16.1)	71.6 (13.6)	69.0 (14.9)
	Pain	80.5 (19.4)	80.7 (20.7)	82.6 (17.1)	78.1 (19.8)
	Perceived health	69.6 (15.6)	71.3 (15.3)	69.9 (14.9)	67.1 (16.7)
	Health change	54.0 (18.6)	53.3 (19.5)	55.1 (19.0)	53.8 (17.1)
GDS, score		3.1 (3.4)	2.5 (2.7)	3.0 (3.6)	4.0 (3.8)
Executive functioning					
Trail-making test	Part A, s	34.4 (13.1)	35.0 (11.9)	34.2 (13.6)	33.6 (14.4)
	Part B, s	74.9 (35.5)	74.2 (30.0)	70.0 (25.8)	80.4 (47.8)
Stroop Color–Word test	Part I, s	50.8 (9.0)	50.1 (7.6)	49.6 (6.9)	52.9 (11.8)
	Part II, s	62.9 (12.5)	61.7 (11.1)	62.3 (11.4)	65.0 (14.9)
	Part III, s	105.2 (32.2)	103.9 (30.8)	102.9 (24.6)	109.2 (39.6)
Stroop interference score, s		48.4 (25.9)	48.0 (26.0)	47.0 (20.5)	50.3 (30.2)
Letter-fluency test, number of words		41.5 (13.6)	43.1 (12.4)	41.1 (12.9)	39.5 (15.8)

6MWT, 6 min walk test; avMETs/day, average metabolic equivalent of tasks per day; BMI, body mass index; EP, emotional problem; GDS, geriatric depression scale; HGS, hand grip muscle strength; MMSE, Mini-Mental State Examination; m-PPT, modified Physical Performance Test; PAL, physical activity level; PP, physical problem; RAND-36, the RAND-36 item health survey; SMM, skeletal muscle mass, sum of lean mass of the four limbs by DXA; SPPB, short physical performance battery; TUG, timed-up-and-go test.
[a]Unless otherwise noted, the observed characteristics are reported with mean (SD) for the total population and per group.
[b]Low education defined as community college or less educated (primary and secondary education).
[c]Sarcopenia score derived from Cruz-Jentoft *et al*.[2]; based on HGS, SMM/height^2, and gait speed.
[d]Frailty score derived from m-PPT score.
[e]Disease categories based on 10th revision of the *International Statistical Classification of Diseases and Related Health Problems* (ICD-10).

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Table 2 Effects of home-based exercise and protein on outcome in older adults

		Randomized groups							Mixed models with interaction effects*			
		CON		HBex		HBex-Pro			Exercise effects (HBex vs. CON)		Exercise + protein effects (HBex-Pro vs. CON)	
Outcome variable[a]		*n*	Mean (SE)	*n*	Mean (SE)	*n*	Mean (SE)		Difference (95% CI)	*P*-value	Difference (95% CI)	*P*-value
Physical functioning												
m-PPT[b] (score)	0 m	91	34.0 (0.2)	65	33.9 (0.3)	68	33.9 (0.3)					
	6 m	81	33.9 (0.3)	56	33.8 (0.3)	47	33.7 (0.3)	Intervention effect	+0.03 (−0.69; 0.75)	0.933	−0.13 (−0.89; 0.62)	0.730
	12 m	77	34.2 (0.3)	46	33.7 (0.4)	43	33.7 (0.3)	Follow-up effect	−0.38 (−1.24; 0.49)	0.396	−0.41 (−1.30; 0.48)	0.362
SPPB (score)	0 m	91	11.3 (0.1)	65	11.4 (0.1)	68	11.2 (0.1)					
	6 m	81	11.3 (0.1)	56	11.4 (0.1)	47	11.2 (0.1)	Intervention effect	−0.06 (−0.33; 0.22)	0.691	−0.02 (−0.30; 0.27)	0.918
	12 m	77	11.3 (0.1)	46	11.2 (0.1)	43	11.2 (0.1)	Follow-up effect	−0.21 (−0.50; 0.08)	0.156	−0.02 (−0.31; 0.28)	0.914
TUG (s)	0 m	91	7.4 (0.2)	64	7.3 (0.3)	68	7.6 (0.2)					
	6 m	81	7.8 (0.2)	55	7.8 (0.3)	46	7.9 (0.2)	Intervention effect	+0.07 (−0.21; 0.34)	0.648	−0.08 (−0.37; 0.21)	0.592
	12 m	77	7.4 (0.2)	46	7.5 (0.3)	42	7.7 (0.2)	Follow-up effect	+0.16 (−0.14; 0.45)	0.290	+0.18 (−0.12; 0.48)	0.245
6MWT (m)	0 m	91	516 (9)	65	512 (10)	67	490 (11)					
	6 m	81	531 (9)	55	529 (10)	47	516 (11)	Intervention effect	+2.21 (−11.7; 16.1)	0.756	+10.8 (−3.9; 25.4)	0.149
	12 m	77	528 (9)	45	528 (10)	41	516 (11)	Follow-up effect	+3.16 (−11.5; 17.9)	0.673	+12.7 (−2.5; 28.0)	0.102
Gait speed (m/s)	0 m	91	1.36 (0.0)	65	1.34 (0.0)	68	1.27 (0.0)					
	6 m	81	1.16 (0.0)	55	1.22 (0.0)	47	1.27 (0.0)	Intervention effect	+0.08 (−0.03; 0.19)	0.163	**+0.20 (0.09; 0.32)**	**0.001**
	12 m	77	1.21 (0.0)	45	1.21 (0.0)	43	1.18 (0.0)	Follow-up effect	+0.02 (−0.10; 0.14)	0.759	+0.06 (−0.05; 0.18)	0.280
PAL (avMETs/day)	0 m	86	1.51 (0.0)	65	1.50 (0.0)	66	1.49 (0.0)					
	6 m	80	1.49 (0.0)	55	1.50 (0.0)	43	1.53 (0.0)	Intervention effect	+0.02 (−0.02; 0.06)	0.290	**+0.06 (0.02; 0.11)**	**0.008**
	12 m	77	1.52 (0.0)	46	1.52 (0.0)	40	1.48 (0.0)	Follow-up effect	+0.01 (−0.03; 0.05)	0.683	−0.01 (−0.06; 0.03)	0.608
HGS-av (kg)	0 m	91	29.9 (1.2)	65	30.0 (1.1)	68	28.4 (1.2)					
	6 m	81	29.5 (1.2)	56	29.5 (1.1)	47	30.3 (1.2)	Intervention effect	−0.08 (−1.37; 1.20)	0.898	**+2.32 (0.97; 3.67)**	**0.001**
	12 m	77	30.0 (1.2)	48	29.5 (1.1)	43	30.0 (1.2)	Follow-up effect	−0.52 (−1.86; 0.82)	0.448	**+1.52 (0.13; 2.91)**	**0.032**
Nutrition and body composition												
Protein intake[c] (g/kg/day)	0 m	84	1.09 (0.0)	63	1.08 (0.0)	65	1.07 (0.0)					
	6 m	81	1.13 (0.0)	55	1.11 (0.0)	45	1.41 (0.0)	Intervention effect	−0.01 (−0.09; 0.08)	0.866	**+0.32 (0.23; 0.42)**	<**0.001**
	12 m	77	1.05 (0.0)	48	1.07 (0.0)	42	1.24 (0.0)	Follow-up effect	+0.03 (−0.06; 0.12)	0.504	**+0.23 (0.13; 0.32)**	<**0.001**
SMM (kg)	0 m	89	20.6 (0.5)	65	21.0 (0.7)	67	20.8 (0.5)					
	6 m	80	20.3 (0.5)	56	20.8 (0.7)	46	20.8 (0.5)	Intervention effect	+0.19 (−0.07; 0.44)	0.154	**+0.33 (0.06; 0.60)**	**0.017**
	12 m	77	20.1 (0.5)	47	20.7 (0.7)	42	20.8 (0.5)	Follow-up effect	+0.19 (−0.08; 0.45)	0.170	**+0.51 (0.23; 0.79)**	<**0.001**
Health status												
RAND-36 PF[b]	0 m	91	83.4 (1.6)	65	85.5 (1.7)	68	82.8 (1.7)					
	6 m	79	83.2 (1.6)	55	86.5 (1.7)	47	85.2 (1.8)	Intervention effect	+1.22 (−2.63; 5.06)	0.536	+2.54 (−1.49; 6.57)	0.216
	12 m	77	84.1 (1.7)	48	85.5 (1.7)	43	82.7 (1.9)	Follow-up effect	−0.69 (−5.32; 3.94)	0.770	−0.75 (−5.55; 4.05)	0.760
RAND-36 SF	0 m	91	88.2 (1.0)	65	88.9 (0.9)	67	86.7 (1.1)					
	6 m	79	88.5 (1.0)	55	88.9 (0.9)	47	89.2 (1.1)	Intervention effect	−0.25 (−5.59; 5.09)	0.926	+2.27 (−3.34; 7.87)	0.428
	12 m	77	87.4 (1.0)	48	86.8 (0.9)	43	85.6 (1.1)	Follow-up effect	−1.27 (−6.83; 4.28)	0.653	−0.24 (−6.00; 5.52)	0.935
RAND-36	0 m	91	77.7 (1.7)	65	80.3 (1.9)	68	76.2 (1.8)					
Fprob[c]	6 m	79	77.5 (1.7)	55	76.6 (1.9)	47	76.7 (1.8)	Intervention effect	−3.45 (−9.91; 3.00)	0.294	+0.72 (−6.03; 7.48)	0.834
	12 m	77	75.9 (1.7)	48	77.7 (1.9)	43	76.4 (1.8)	Follow-up effect	−0.67 (−7.39; 6.04)	0.844	+2.01 (−5.00; 8.99)	0.574

(*Continues*)

Table 2 (continued)

Outcome variable[a]		Randomized groups							Mixed models with interaction effects*			
		CON		HBex		HBex-Pro			Exercise effects (HBex vs. CON)		Exercise + protein effects (HBex-Pro vs. CON)	
		n	Mean (SE)	*n*	Mean (SE)	*n*	Mean (SE)		Difference (95% CI)	*P*-value	Difference (95% CI)	*P*-value
RAND-36	0 m	88	86.9 (1.2)	65	85.2 (1.4)	67	83.2 (1.4)					
Eprob[c]	6 m	79	84.0 (1.2)	55	83.2 (1.4)	47	83.4 (1.4)	Intervention effect	+0.86 (−4.81; 6.53)	0.766	+3.12 (−2.85; 9.08)	0.306
	12 m	77	84.2 (1.2)	48	85.7 (1.4)	43	81.4 (1.4)	Follow-up effect	+3.21 (−2.70; 9.12)	0.287	+0.89 (−5.24; 7.03)	0.775
RAND-36	0 m	91	81.4 (1.1)	65	80.3 (1.1)	67	77.5 (1.0)					
Mental[c]	6 m	79	82.2 (1.1)	55	79.5 (1.1)	47	76.5 (1.0)	Intervention effect	−1.61 (−5.25; 2.02)	0.384	−1.85 (−5.68; 1.97)	0.342
	12 m	76	83.5 (1.1)	48	81.5 (1.1)	43	76.8 (1.0)	Follow-up effect	−0.89 (−4.67; 2.90)	0.646	−2.78 (−6.71; 1.16)	0.166
RAND-36	0 m	91	80.6 (1.2)	65	81.9 (1.3)	67	78.9 (1.3)					
Pain[c]	6 m	79	82.6 (1.2)	55	82.1 (1.3)	47	82.4 (1.3)	Intervention effect	−1.66 (−7.56; 4.24)	0.581	1.60 (−4.62; 7.81)	0.615
	12 m	77	81.4 (1.2)	48	80.1 (1.3)	43	79.3 (1.3)	Follow-up effect	−2.61 (−8.76; 3.55)	0.406	−0.42 (−6.81; 5.97)	0.898
RAND-36	0 m	91	72.5 (1.3)	65	71.8 (1.3)	67	69.2 (1.2)					
Vitality[c]	6 m	79	74.5 (1.3)	55	72.6 (1.3)	47	69.5 (1.2)	Intervention effect	−1.25 (−5.23; 2.72)	0.537	−1.75 (−5.93; 2.43)	0.411
	12 m	76	73.8 (1.3)	48	71.8 (1.3)	43	67.8 (1.2)	Follow-up effect	−1.43 (−5.57; 2.70)	0.508	−2.77 (−7.07; 1.53)	0.207
RAND-36	0 m	91	70.7 (1.2)	65	70.1 (1.2)	67	67.6 (1.5)					
Health[c]	6 m	79	71.2 (1.2)	55	69.0 (1.2)	47	69.5 (1.5)	Intervention effect	−1.65 (−5.66; 2.36)	0.420	+1.33 (−2.90; 5.55)	0.538
	12 m	76	68.9 (1.2)	48	71.0 (1.2)	42	67.4 (1.5)	Follow-up effect	+2.58 (−1.60; 6.77)	0.226	+1.52 (−2.86; 5.89)	0.497
RAND-36	0 m	90	53.4 (1.2)	64	54.7 (1.3)	66	54.0 (1.4)					
Health change[b]	6 m	79	49.5 (1.0)	55	55.3 (1.0)	47	57.2 (1.3)	Intervention effect	*+4.73 (−0.32; 9.78)*	*0.066*	**+6.93 (1.62; 12.2)**	**0.011**
	12 m	77	48.6 (1.0)	48	53.1 (1.3)	43	51.4 (1.3)	Follow-up effect	+3.57 (−2.91; 10.0)	0.280	+1.83 (−4.90; 8.55)	0.594
GDS (score)	0 m	85	2.8 (0.3)	63	3.0 (0.4)	65	3.9 (0.4)					
	6 m	81	2.8 (0.3)	56	2.9 (0.4)	43	3.6 (0.4)	Intervention effect	−0.08 (−0.79; 0.62)	0.816	−0.29 (−1.04; 0.47)	0.459
	12 m	74	2.7 (0.3)	47	2.5 (0.4)	42	4.5 (0.4)	Follow-up effect	−0.40 (−1.15; 0.33)	0.278	+0.71 (−0.06; 1.48)	*0.071*
Executive functioning												
TMT Part A[b] (s)	0 m	91	34.9 (0.9)	65	34.1 (1.2)	68	33.8 (1.4)					
	6 m	81	34.2 (0.9)	56	31.1 (1.2)	47	31.6 (1.2)	Intervention effect	−2.37 (−5.48; 0.73)	0.134	−1.63 (−4.91; 1.65)	0.330
	12 m	77	31.9 (0.9)	47	31.5 (1.1)	43	29.6 (1.1)	Follow-up effect	+0.33 (−3.33; 4.00)	0.858	−1.37 (−5.14; 2.41)	0.478
TMT Part B[b] (s)	0 m	90	74.4 (2.7)	64	71.2 (2.7)	68	79.4 (4.9)					
	6 m	78	71.6 (2.5)	56	67.2 (2.4)	47	73.4 (4.4)	Intervention effect	−1.43 (−8.45; 5.59)	0.690	−2.80 (−10.2; 4.58)	0.457
	12 m	76	70.4 (2.2)	47	62.3 (2.3)	42	72.6 (4.0)	Follow-up effect	−5.26 (−12.4; 1.87)	0.148	−1.85 (−9.23; 5.53)	0.623
SCW Part I (s)	0 m	91	50.2 (0.8)	64	49.7 (0.7)	68	52.7 (1.2)					
	6 m	81	50.9 (0.8)	55	48.4 (0.7)	47	50.6 (1.2)	Intervention effect	**−2.06 (−3.66; −0.46)**	**0.012**	**−2.85 (−4.53; −1.17)**	**0.001**
	12 m	76	50.6 (0.9)	47	47.8 (0.7)	43	50.0 (1.2)	Follow-up effect	**−2.34 (−4.02; −0.66)**	**0.006**	**−3.15 (−4.89; −1.42)**	**<0.001**
SCW Part II (s)	0 m	91	61.8 (1.1)	64	62.2 (1.2)	68	64.9 (1.7)					
	6 m	81	61.9 (1.1)	55	60.0 (1.2)	47	63.3 (1.7)	Intervention effect	**−2.38 (−4.20; −0.57)**	**0.010**	*−1.66 (−3.56; 0.24)*	*0.087*
	12 m	77	60.7 (1.1)	47	59.5 (1.2)	43	62.9 (1.7)	Follow-up effect	*−1.64 (−3.54; 0.26)*	*0.091*	−0.84 (−2.80; 1.12)	0.399
SCW Part III (s)	0 m	91	104 (2.7)	64	103 (2.8)	68	109 (3.9)					
	6 m	81	101 (2.7)	55	98.2 (2.8)	47	100 (3.9)	Intervention effect	−1.47 (−6.34; 3.40)	0.555	**−5.21 (−10.3; −0.10)**	**0.046**
	12 m	77	102 (2.7)	47	97.4 (2.8)	43	102 (3.9)	Follow-up effect	−3.71 (−8.81; 1.38)	0.153	**−5.51 (−10.8; −0.25)**	**0.040**

(*Continues*)

Table 2 (continued)

Outcome variable[a]		Randomized groups						Mixed models with interaction effects*				
		CON		HBex		HBex-Pro			Exercise effects (HBex vs. CON)		Exercise + protein effects (HBex-Pro vs. CON)	
		n	Mean (SE)	*n*	Mean (SE)	*n*	Mean (SE)		Difference (95% CI)	*P*-value	Difference (95% CI)	*P*-value
SIS[b] (score)	0 m	91	48.0 (2.3)	64	47.1 (2.1)	68	50.0 (3.0)					
	6 m	81	44.4 (2.1)	55	43.9 (2.1)	47	43.0 (2.4)	Intervention effect	+0.02 (−6.13; 6.16)	0.996	−3.71 (−10.1; 2.69)	0.256
	12 m	76	45.8 (2.2)	47	43.7 (2.3)	43	44.4 (2.1)	Follow-up effect	−1.74 (−12.3; 8.80)	0.746	−3.71 (−14.6; 7.20)	0.505
Letter-fluency test (number)	0 m	91	42.9 (1.0)	65	41.3 (1.3)	68	39.6 (1.7)					
	6 m	81	42.9 (1.0)	56	43.3 (1.3)	47	42.2 (1.7)	Intervention effect	+1.96 (−0.66; 4.58)	0.143	+2.64 (−0.12; 5.40)	*0.061*
	12 m	77	44.5 (1.0)	47	45.3 (1.3)	43	44.0 (1.7)	Follow-up effect	+2.37 (−0.39; 5.12)	*0.092*	+2.84 (−0.00; 5.69)	*0.050*

6MWT, 6 min walk test; BMI, body mass index; GDS, geriatric depression scale; HGS, hand grip muscle strength; m-PPT, modified Physical Performance Test; PAL, physical activity level; RAND-36 PF, RAND-36 health survey physical functioning score; RAND-36 SF, RAND-36 health survey social functioning score; SCW, Stroop Color–Word test; SIS, Stroop interference score; SMM, skeletal muscle mass; SPPB, short performance battery; TMT, trail-making test; TUG, timed-up-and-go test.

[a]Unless otherwise noted, the observed data are reported as estimated marginal means (SE) values including the random effects within the model.

[b]Time was added as random slope, three-level model, covariance exchangeable or unstructured.

[c]Covariate BMI was added.

*P-values for the comparison among the groups from baseline to 6 and 12 months were calculated with the use of mixed-model analysis of repeated measures and are reported when the overall P-value was <0.05 for the interaction over time. Fixed factors included time and time * group interaction. Random intercepts included subject and cluster. Unless otherwise noted, covariates Age, BMI, Mini-Mental State Examination (MMSE), and Sex were added.

(−1.64; P = 0.091). The most demanding Part III showed, furthermore, a significant intervention effect and follow-up effect for HBex-Pro (−5.21; P = 0.046|−5.51; P = 0.040), and letter fluency resulted in trends for both intervention groups (*Table* 2).

Adherence to the interventions

Table S1 shows no significant differences between the groups for accomplished weeks of coached intervention. The average days of exercise and the average number of exercises per week were significantly higher in HBex compared with HBex-Pro [3.31 (1.6) vs. 2.47 (1.8); P = 0.006| 16.03 (12.8) vs. 9.23 (8.7); P = 0.001]. The adherence of the exercise protocol (≥2 days/week) was accomplished by 75% in HBex compared with 49% in HBex-Pro. Subsequent per-protocol analysis for adherend participants showed similar results to intention-to-treat analysis and participant characteristics (Information *Tables* S2 and S3). App results during the intervention period are presented in *Figure* S1.

The a priori dietary protein intake target of a minimum of 1.2 g/kg/day was achieved by 69% in HBex-Pro, 35% in HBex, and 41% in CON. The optimal target of 1.5 g/kg/day was achieved by 40% in HBex-Pro, 13% in HBex, and 14% in CON. The HBex-Pro participants received significantly more total coach contacts [18.5 (6.0) vs. 10.2 (3.8); $P < 0.001$] and similar total exercise coach contacts [9.40 (3.9) vs. 10.16 (3.8); P = 0.266], with 9.06 (2.6) total diet coach contacts (*Table* S1).

Discussion

In this VITAMIN trial, we were unable to show an effect of a new HBex and dietary protein intervention on physical performance of community-dwelling older adults, based on the m-PPT. Other physical performance tests (SPPB, 6MWT, or TUG) also lacked effect, while gait speed and PAL showed maintenance or improvements over 6 months in the combined exercise+protein group (HBex-Pro). The control group shows age-related decline in muscle mass of 2.5% at 12 months, contributing to development of sarcopenia. Improvements in exercise and protein intake resulted in maintenance of muscle mass at 12 months and supported improvement in muscle strength, gait speed, and physical activity.

Previous studies showed the average rate of 0.5–2% annual loss of muscle mass in older adults.[33,34] Our control group showed a slightly higher decline of muscle mass over a year. This observed decline might be attributed by prevalence of several medical conditions, physical characteristics, nutritional status, and the periods of incidental physical inactivity.[35]

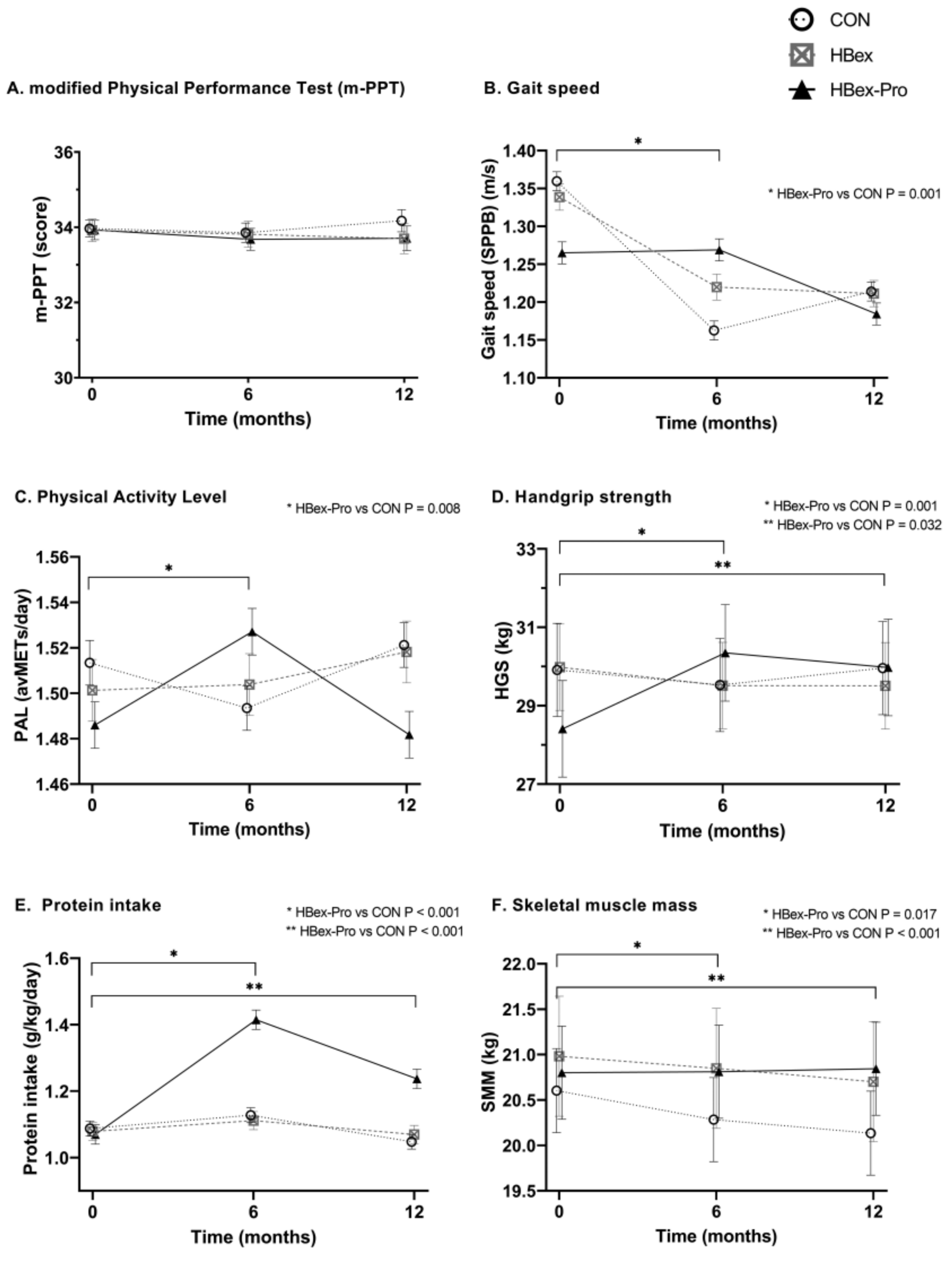

Figure 2 Outcomes on physical functioning and nutritional status. (A) Modified Physical Performance Test (m-PPT). (B) Gait speed. * HBex-Pro vs. CON $P = 0.001$. (C) Physical Activity Level. * HBex-Pro vs. CON $P = 0.008$. (D) Handgrip muscle strength. * HBex-Pro vs. CON $P = 0.001$. ** HBex-Pro vs. CON $P = 0.032$. (E) Protein intake. * HBex-Pro vs. CON $P < 0.001$. ** HBex-Pro vs. CON $P < 0.001$. (F) Skeletal muscle mass. * HBex-Pro vs. CON $P = 0.017$. ** HBex-Pro vs. CON $P < 0.001$. (A–F) Outcomes on physical functioning and nutritional status were assessed and reported as estimated marginal means with indicated standard error bars. The *P*-values, derived from the linear mixed models between intervention groups and CON, are also shown. The months represent the time points (0, 6, and 12 months) at which the measurements were assessed. CON, no intervention, control; HBex, blended home-based exercise intervention; HBex-Pro, HBex with dietary protein counselling.

As far as we know, this is the first large RCT on the effects of a blended home-based exercise programme and protein counselling on physical performance in active older adults. The combination of supervised resistance exercise with protein supplementation is known as the most effective strategy to improve muscle function in older adults.[18,19,36] Our findings indicate opportunities for a more functional, flexible, and less time-consuming[37] home-based strategy in contrast to supervised resistance exercise.

Our community-dwelling older adults were able to generate a mean number of 12.5 (11.3) functional exercises per week in almost three exercise days per week. In addition, the adherence to the exercise regime (≥2 days/week) in 26 weeks was high (49–75%) in comparison with that of other studies engaging unsupervised home-based exercise.[12,38] The difference between the adherence of the two groups can be attributed to the combined behaviour change in the exercise + protein group vs. the exercise-only group.

Prolonged use of this blended home-based exercise programme, therefore, has potential for community-dwelling older adults to remain physically active. Low physical activity and decreased gait speed are predictors of ADL disability in community-dwelling people.[39] The observed intervention effects for the exercise+protein group on gait speed and physical activity indicate a preventive strategy for loss of ADL functioning. These effects might be attributed to the blended design and the combined exercise and nutrition behaviour change, because complex and multidomain interventions show more benefits on functional outcomes in older adults.[7,40,41]

Besides, it is encouraging that several changes were observed in executive functioning, especially in the Stroop Color–Word test. This might be related to the e-health application, which is designed for our aged end-user with starting visual impairments. The association between physical activity and exercise training with executive functioning is well established.[42] Moreover, the self-reported perceived health change was also significantly improved, which indicates a more general health impact of the intervention in community-dwelling older adults. The observed effects might be provided by the combination (blending) of the e-health application and personalized coaching to change self-regulation, competence, and motivation.[43,44]

According to the WHO Healthy Ageing strategy, there is urgency for innovative sustainable exercise and nutrition interventions with an interdisciplinary approach on physical functioning in older adults[45]; therefore, our newly developed interventions are a major strength. The imbedded functional task exercises showed to be a beneficial, feasible, and complementary strategy[46] in this population with diverse medical conditions. As well, the population size, even distribution of the clusters, study duration, and high adherence support the methodological quality of the cluster RCT study.

Limitations can be pointed out as well. First, the previously mentioned outcomes m-PPT, SPPB, and RAND-36 summary scores all had ceiling effects. As the intervention was aimed to be implemented nationwide, we did not select participants on performance level. Participants had a fairly good performance at baseline, as shown in the scale scores at baseline from m-PPT, SPPB, and RAND-36. This might have nihilated improvement in performance but maintained other health-related functions. Second, results of this study may not be generalizable to those older adults without a regular weekly exercise programme. Third, the dropout was higher in the combined intervention and might be attributed to intensity of the combined lifestyle change. As comparable studies are lacking, future studies in community-dwelling older adults, including an interdisciplinary approach with exercise, nutrition, and e-health, are therefore recommended.

In conclusion, this HBex and dietary protein intervention did not change physical performance (m-PPT) in community-dwelling older adults. However, changes in gait speed, PAL, muscle mass, and strength accompanied by increased dietary protein were observed at 6 months. Effects on protein intake, muscle mass, and strength sustained after termination of the personalized coaching at 12 months.

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Conflict of Interest

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Ethical standards

The authors certify that they comply with the ethical guidelines for authorship and publishing of the *Journal of Cachexia, Sarcopenia, and Muscle*.[47]

Contributors

JvdH and SM had full access to all of the data after the study, CvD had full access to all of the data during the study, and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed to interpreting the results and drafting and revising the article. JvdH, SM, CvD, MT, BV, BK, RE, and PW were involved in the study concept and design of the trial protocol. SM, BV, BK, RE, and PW contributed to the funding application of the trial. JvdH, SM, and CvD carried out project administration, technical resources, and primary investigation. SM and BK supervised the design of the e-health infrastructure. JvdH and CvD were involved in study coordination. JvdH, MT, and PW were study supervisors, whereas PW was the principal investigator of the trial. Formal analysis was executed by JvdH, GtR, and PW. All authors read and approved the final manuscript.

Online supplementary material

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Data S1. Functional training program

Data S2. Coaching schedule of the interventions

Figure S1. App data of home-based exercise for both intervention groups

Table S1. Intervention, app and coaching results of 26 weeks

Table S2. Effects of exercise and protein on outcome in older adults - per protocol analysis

Table S3. Baseline characteristics of the participants in per protocol analysis

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