Title: Community-based exercise enhanced by a self-management programme to promote independent living in older adults: a pragmatic randomized controlled trial

Abstract

Background: Older adults face several modifiable barriers for engaging in physical activity (PA) programmes such as incontinence, loneliness, and fear of falling. Enhancing PA programmes with behavioural components to support self-management of such barriers may increase the effectiveness to preserve functional capacity and independent living.

Objective: This study aimed at assessing the effects of a complex active lifestyle intervention (CALSTI) on objective and self-report measures of functional capacity and disability in community-dwelling older adults.

Subjects and methods: 215 older adults (79.9 ± 0.4 years) at increased risk of functional decline were randomly allocated to i) CALSTI consisting of 12-weeks progressive explosive resistance training (24 sessions) enhanced by a 24-week multi-factorial self-management programme (8 sessions), or ii) an extended version of the self-management intervention (SEMAI; 12 sessions) to reflect a reinforcement of usual care. The interventions were embedded in a nationally-regulated preventive care pathway. Blinded assessors collected primary (the Short Physical Performance Battery; SPPB) and secondary outcome data (self-reported difficulty in activities of daily living, the short version of the Late-Life Function and Disability Index, and the EQ-health VAS scale) at baseline and after 12- and 24 weeks. **Results:** after 24 weeks, CALSTI led to a clinically superior increase in SPPB compared to SEMAI (+0.77 points, $p<0.01$), and the CALSTI group also demonstrated improvements in selected self-reported outcomes.

Conclusions: A novel complex exercise and multi-factorial self-management intervention embedded in preventive care practice had large and clinically meaningful effects on a key measure of functional capacity and predictor of disability.

Background

Older adults currently constitute the most inactive population group in Europe(1), and considering the overwhelming benefits of physical activity (PA) for health, well-being, function, and prevention of disability(2-4), it has become a key primary prevention target to increase the PA-level of the older population(5, 6). Behaviour-change strategies used in combination with exercise may successfully contribute to this (7-9). Especially, self-regulation strategies including personal goal-setting and self-monitoring, capability enhancing strategies such as visits to resources where exercise can take place after exercise intervention(8), and strategies to increase self-efficacy and positive expectancies to the outcome of PA(10, 11), have been previously linked to increasing PA in older adults.

However, maintenance of PA-level and the desired health benefits after removing the intervention period remains a challenge(7), and it has been suggested that combined exercise and behaviour-change interventions should take whole-system approaches(7). This implies that when designing an intervention this should be person-centred (i.e., tailored to participant's goals, preferences, and needs), and be linked to the available resources in the community and health care sector. Also, interventions should incorporate earlier identified promoters of long-term engagement with PA-programmes including nearby facilities, low fees, enjoyment of exercise, and use formats that spur social support and commitment(12-14). Finally, long-term effects may increase by adding behaviour-change strategies aiming to simultaneously tackle multiple risk-factors for functional decline and disability (15, 16), and well-known barriers for PA such as inadequate health literacy(17), incontinence(18), loneliness(19), chronic pain(20), fear of falling(21), and lack of company, interest or motivation for exercising(13, 22).

This article presents an innovative whole-system oriented intervention combining 12 weeks group-based progressive exercise in parallel with a 24-week multi-factorial self-management programme to tackle several potential barriers for PA.

The aim of the present study is to assess the effects of this intervention in a routine preventive care framework for community-dwelling older adults on objective and self-report measures of functional capacity, and self-report disability.

Methods

This article reports primary and secondary outcomes from a pragmatic trial of the Welfare Innovation in Primary Prevention (WIPP) project funded by the European INTERREG 5a program to support development and innovations in the German-Danish boarder regions(23). The trial followed a parallel, two-armed randomized controlled design. Prospective participants received verbal and written information about the random allocation, intervention, and testing procedures prior to agreeing to participate, and they signed written consent to share their anonymized data for scientific purposes. The reporting followed the extended CONSORT statements for pragmatic studies(24, 25) and the TIDIER checklist(26).

Pragmatic study model and recruitment pathway

To ensure high ecological validity(27), we developed a pragmatic study model that enabled effectiveness of the interventions to be evaluated in a naturalistic preventive practice framework. A detailed description of the model is available in supplemental material S1. In summary, the study intervention was co-created with key stakeholders, including representatives from academia, primary care providers, community partners, and older adult's organizations.

To broaden the reach and obtain a more specific recruitment of the intended at-risk target group, participants were recruited through a well-established nationally regulated preventive pathway since 1996: the Preventive Home-Visits (PVH)(28, 29). This pathway dictates that each individual aged 75 years or older (65 for vulnerable subgroups) who does not receive personal care services on a regular basis is entitled to receive a PHV by health care personnel employed in the municipality(28). The aim of the PHV is to uncover potential problems that may threaten well-being and independency and provide information about relevant resources in the community, public health care sector, and by third-party actors(29).

Invitation-letters for the PHV are automatically sent through a secure email system and through phone calls and post for citizens who do not have such digital systems. Occasionally, secondary pathways (e.g., local media, info-meetings) are used to recruit individuals at high-risk who do not respond to the letters.

All study phases (i.e., recruitment, data collection, intervention) were fully run by the municipalities (i.e., primary care providers), who recruited trainers and assessors among their existing health care personnel, predominantly nurses and occupational therapists.

Participants

Over a two-year period, all citizens who were eligible to the PHV and living in three danish municipalities received an invitation to WIPP-screening within their routine invitation-letter for the PHV. The *WIPP-Screening* was developed to: i) early identify citizens at greater risk of functional loss, and ii) enable timely and tailored action-plans to modify such risk. It covers physical, mental, and social risk factors adopting the International Classification of Health, Functioning and Disability framework(30). Inclusion criteria included ≥1 of the following risk

factors: (1) low PA (moderate to vigorous PA ≤1day/week while daily sitting time ≥8 hours); (2) high fatigability (Pittsburgh Fatigability Score ≥15(31)); (3) recurrent falls (≥2 falls over the past year); (4) pain interference with daily activities (Brief Pain Inventory interference score ≥20(32)); or (5) low functional capacity (short physical performance battery; SPPB-score ≤9(33, 34)). Participants with SPPB-score >10 or physically active ≥3 days/week while daily sitting time <5 hours were excluded irrespective of whether they met one of the other eligibility criteria. Occasionally, ineligible relatives were allowed to participate in interventions if their eligible partner needed support (e.g., transport), however, they were excluded from the analysis.

Data collection, randomization, and blinding procedures

Eligible participants were invited to a baseline assessment, followed by sealed random allocation (supplemental material S2) to: (i) the Complex Lifestyle Intervention (CALSTI) and (ii) usual care enhanced with the self-management intervention (SEMAI). Participants were also handed out a battery of self-report questionnaires to complete at home and be returned to trainers at the following group-session, or by post using pre-paid envelopes. Collection of intervention data was repeated after 12 and 24 weeks. Follow-up assessors were blinded to group-allocation, and participants were instructed not to reveal any information that may unmask their allocation.

Interventions

Figure 1 Schedule of interventions and data collection

Week	SEMAI	CALSTI	
-2 to 0	Baseline assessments 1 hour performance-based test session + Battery of questionnaires handed out		
1	1.5 h SMS	1.5 SMS	2 x 1 h Ex
	Baseline questionnaires retrieved at SMS-session		
2	1.5 h SMS		2 x 1 h Ex
3	1.5 h SMS	1.5 h SMS	2 x 1 h Ex
4	1.5 h SMS		2 x 1 h Ex
5			2 x 1 h Ex
6	1.5 h SMS	1.5 h SMS	2 x 1 h Ex
7			2 x 1 h Ex
8	1.5 h SMS		2 x 1 h Ex
9			2 x 1 h Ex
10	1.5 h SMS		2 x 1 h Ex
11		1.5 h SMS	2 x 1 h Ex
12	1.5 h SMS		2 x 1 h Ex
13	12-week assessments 1 hour performance-based test session + Battery of questionnaires handed out		
14			
15	1.5 h SMS	1.5 h SMS	
	12-week questionnaires retrieved at SMS-session		
16			
17			
18	1.5 h SMS	1.5 h SMS	
19			
20			
21	1.5 h SMS	1.5 h SMS	
22			
23			
24	1.5 h SMS	1.5 h SMS	
25	24-week assessments 1 hour performance-based test session + Battery of questionnaires handed out		
26 to 27	24-week questionnaires retrieved by post		
Total	**18 h SMS**	**12 h SMS**	**24 h Ex**

SMS self-management strategy programme; Ex Exercise Programme; h hours

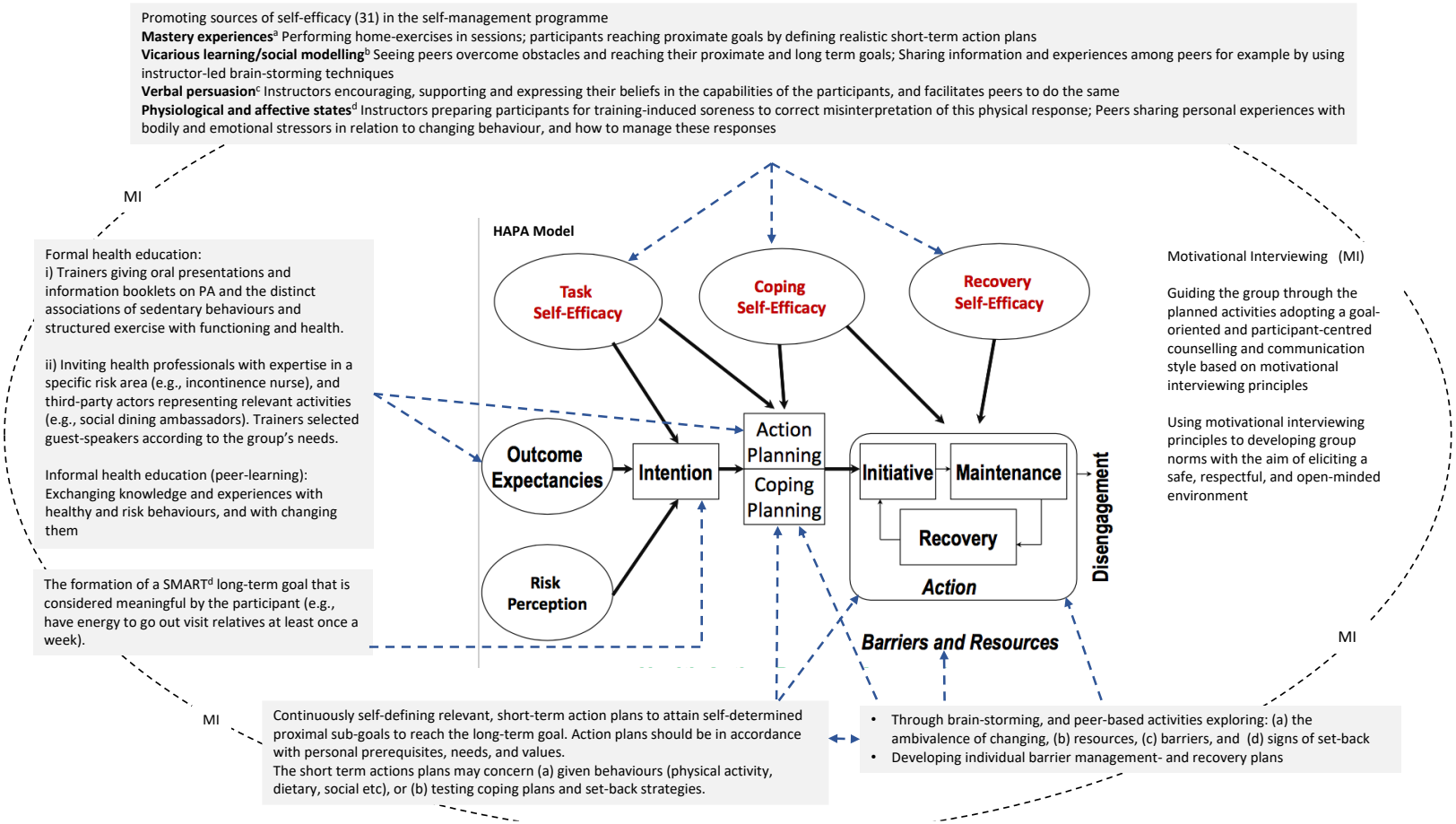
CALSTI was designed with two group-based components starting off in parallel: (a) 12-week (24 sessions) progressive exercise component; and (b) 24-week multi-factorial self-management programme (8 sessions) (figure 1). Interventions took place in diverse community-settings including activity centres, housing organizations, and sports clubs. Detailed description of intervention protocols is available in supplemental material S3. Briefly, the exercise component aimed to enhance functional capacity primarily through progressive high-intensity explosive-type resistance training following a protocol from a previous study(35) that was modified to fit the

heterogenic availability of exercise equipment. Sessions included also progressive balance and high-intensity aerobic exercise.

The self-management programme aimed at empowering participants to tackle key modifiable risk factors for functional loss and barriers for engaging in PA. This was operationalized by (i) supporting self-management skills (i.e. problem solving, decision making, resource utilization, and taking action(36)); (ii) mobilizing use of activities (e.g. senior sports clubs, social eating); and (iii) identifying supportive resources in the personal network and local community. Formal and informal (i.e., peer-based) educational strategies (presentations by the instructor, brains-storming techniques) were used to raise awareness about personal risks factors and opportunities to act on them. This facilitated participants to focus on the risk factors they each perceived most relevant, enabling a more individualised programme. The programme was manualized, and drew from theoretical frameworks and approaches based on Social Cognitive Theory(37), focusing on self-efficacy(38) as the major determinant of successful behaviour-change process. The inclusion and temporal progress of components (e.g. health education, barrier management) was guided by the Health Action Process Approach (HAPA)(33, 34) (illustrated in figure 2). Trainers led the sessions adopting a goal-oriented and participant-centred counselling and communication style based on motivational interviewing principles(39).

The SEMAI intervention included the self-management programme as in CALSTI with four additional sessions dedicated to gain mastery experiences with exercising by i) visiting local exercise facilities that offer activities for older adults, ii) practising home-exercises at the sessions, iii) exploring local walking routes and outdoor exercise facilities (two sessions).

Figure 2 Scheme of components in the self-management programme and how they map to the Health Action Process Approach (HAPA)



Legend figure 2. Centrally: The Health Action Process Approach (HAPA) model with two temporal phases: the *Motivation phase* that closes with forming a long-term goal, and the *Action phase* which includes planning, action, and maintenance. Ovals illustrate HAPA-determinants of successful *Motivation and Action phases*, with self-efficacy being the major predictor in both phases (Schwarzer, R., Applied Psychology, 2008(40, 41)).
The toned text boxes list behavioural components in the self-management programme (e.g., health education) and examples of activities representing each component (e.g. information booklets)
Stippled arrows illustrate how the active components in the self-management programme map to the elements in the HAPA model (e.g., task self-efficacy).
[d]SMART: Specific, Measurable, Achievable, Realistic, Timely.

Outcomes

Primary outcome

The primary outcome of this study was functional capacity assessed by the SPPB(42) which was earlier shown to predict home care service utilization(34, 43), nursing home admission(42), disability(44) and mortality(42, 45). The SPPB consists of 3 tests (gait, chair-rise, and balance) each scored from 0 to 4 and summed into a total score of maximum 12 points (best performance). Previous data from Perera and colleagues (2006)(46) indicate that to detect a small (0.5±1.48 point) and substantial (1±1.48 point) meaningful change in SPPB-score, minimum numbers of 138 and 35 participants per group respectively are needed for 80% power in a between group comparison.

Secondary outcomes

Secondary outcomes included self-reported function and disability assessed by the sum of difficulty in 5 ADL/IADL items(47), and the short form of the Late-Life Function and Disability Instrument (SF-LLFDI)(48). LLFDI consists of two disability-subscales measuring *frequency* of (SF-LLFDI-DF) and *limitation* in (SF-LLFDI-DL) participation in major life tasks and social roles, and one function sub scale (SF-LLFDI-FU) assessing inability to perform discrete physical tasks)(48). Self-reported health state was assessed the EQ-health VAS score(49). Secondary outcomes are described in detail in supplemental material S4.

Statistics

Key socio-demographic variables were described using mean and standard deviations (SD) or counts (n) and proportions (%) for continuous and categorical variables, respectively. An intention-to-treat approach in participants with baseline data for the outcome of interest was used to test

the hypothesis in this study. A detailed description of the statistical methods is available in the supplemental material S5. Briefly, the core principles in the statistical analysis were linear mixed models, and multiple imputation using chained equations. Missing mechanisms were tested, and we found that baseline data were missing at random (supplemental s-tables 2 and 3).

To investigate the validity of the multiple imputation model, the distribution and ranges of the imputed values were checked against the observed data, and sensitivity analysis on observed data were conducted (s-table 8). All models were adjusted for age, sex, and baseline value of the outcome being tested. We used Stata/IC 16.1 for Mac (StataCorp LCC, 2019) and did statistical testing at a 2-tailed alpha level of 0.05.

Figure 3 Participant flow

PLEASE INSERT FIRST FIGURE IN APPENDIX - ATTACHED AS A SEPARATE PDF DOCUMENT: "figure 3 Participant flow"

Results

Participants

Out of 1406 screened participants, 607 were eligible for this analysis and 215 (35%) of them agreed to be randomly assigned to either CALSTI (n=113) or SEMAI (n=102) interventions (figure 2 and supplemental material S6, stable 6 and 7). Most loss-to-follow up happened before week 12. Loss-to-follow-up was associated with lower baseline SPPB-score in the CALSTI group (6.5±0.5 vs 8.3±2.2, p<.001), but not with any descriptive variable (age, sex, education or living status, p>0.05). Participants mean age was 80 years (range 65-93), 54% lived alone, and the majority were women and had completed at least basic education. A larger share of SEMAI participants reported interference of pain in daily activities and SEMAI had lower baseline SF-LLFDI function (table 1).

Table 1 Baseline characteristics by intervention group

	Overall (n=215)	SEMAI (n=102)	CALSTI (n=113)	Missing data n (%) SEMAI	Missing data n (%) CALSTI
Descriptive variables					
Age, years	79.9 ± 0.4	80.7 ± 0.6	79.2 ± 0.5	0 (0)	0 (0)
Female sex	140 (68)	62 (61)	78 (69)	0 (0)	0 (0)
Living alone	116 (54)	47 (46)	69 (61)	29 (28)	12 (11)
Mandatory school as highest level of completed education	74 (34)	29 (28)	45 (40)	31 (30)	14 (12)
Body Mass Index, kg/cm^2 [a]	28.9 ± 5.5	28.4 ± 5.4	29.3 ± 5.6	1 (1)	1 (1)
Chronic conditions ≥2[b]	61 (28)	31 (30)	30 (27)	3 (3)	2 (2)
Study outcomes					
Short Physical Performance Battery, score 0 – 12	7.7 ± 2.3	7.5 ± 2.3	7.9 ± 2.3	0 (0)	0 (0)
SF-LLFDI disability frequency, score 8 – 40	28.5 ± 4.4	27.3 ± 4.2	29.3 ± 4.4	39 (38)[§]	15 (13)
SF-LLFDI disability limitation, score 8 – 40	31.5 ± 6.1	30.7 ± 6.3	32.1 ± 5.9	40 (39)[§]	27 (24)
SF-LLFDI function, score 15 - 75	49.0 ± 10.7	47.1 ± 10.6	50.2 ± 10.6*	41 (40)[§]	14 (12)
Difficulty in IADL/ADL, summed score 0 – 20[c]	3.5 ± 3.5	3.7 ± 3.6	3.4 ± 3.5	32 (31)[§]	11 (10)
EQ health VAS, score 0-100 (mean ± SD)	60.0 ± 17.0	58.5 ± 18.0	60.9 ± 16.4	33 (29)[§]	54 (53)

Between group differences are investigated using parametric and non-parametric methods as appropriate
Data is presented as number and proportion of total or group (n (%)) for categorical outcomes, and mean (SD) for continuous outcomes
*Significant group differences p<0.05
SPPB = Short Physical Performance Battery; SF-LLFDI = Short Form of the Late Life Function and Disability Index. (I)ADL = (Instrumental) Activities of Daily Living; EQ-health VAS = the EQ-5D Visual Analogue Scale for self-reporting health status
[§] Proportion of missingness is significantly different between groups
a) Calculated from body mass and height assessed at baseline using calibrated equipment
b) Data collected a screening as part of the preventive home visit
c) lower scores represent less ADL difficulty

Primary outcome

Significant group x time interactions revealed that SPPB-score increased 1.16 points more in the CALSTI compared to the SEMAI group during week 1-12 (p<0.001), and 0.77 points more over the total duration of the 24-week intervention (p=0.04) (table 2). Within-group analysis indicated that participants in CALSTI increased their SPPB-score by 1.52 point (19.7% p<0.001;) after 12 weeks, and this level remained unchanged after 24 weeks (p=0.63). The SEMAI group also improved during intervention although this did not reach significance until after 24 weeks (0.82 points, 11.4%; p>0.001)) with the largest increase taking place from week 12 to 24 (0.46 points, 95% CI:

0.06–0.86; p=0.025, not displayed). Changes were similar across intervention sites as demonstrated by a minimal intra cluster correlation (ICC <0.1). Sensitivity analysis on observed data only largely replicated group x time estimates from intention-to-treat analysis (s-table 7)

Table 2 Adjusted balanced means and changes from linear mixed model analyses comparing outcome scores over time by an interaction between intervention group and time

			Change from baseline		
	SEMAI Mean (95% CI)	CALSTI Mean (95% CI)	Δ SEMAI Mean (SE)	Δ CALSTI Mean (SE)	Δ CALSTI − Δ SEMAI Mean (95% CI)
SPPB-score, 0-12 (SEMAI n=102, CALSTI n=113)					
Baseline	7.70 (7.44 – 7.96)	7.72 (7.47 – 7.97)			
12 weeks	8.06 (7.68 – 8.44)	9.24 (8.95 – 9.52)	0.34[€] (-0.06 – 0.78)	1.52[#] (1.19 – 1.84)	1.16[#] (0.64 - 1.68)
24 weeks	8.52 (8.06 – 8.99)	9.31 (9.02 – 9.60)	0.82[#a] (0.33 – 1.31)	1.59[#] (1.26 – 1.92)	0.77[#] (0.20 – 1.34)
SF-LLFDI disability frequency (DF), score 8-40 (SEMAI n=63, CALSTI n=98)					
Baseline	28.24 (27.55 - 28.93)	28.69 (28.14 - 29.24)			
12 weeks	28.81 (27.94 - 29.67)	29.15 (28.57 - 29.72)	0.57 (-0.41 - 1.55)	0.45 (-0.23 - 1.14)	-0.11 (-1.31 – 1.08)
24 weeks	28.14 (27.21 - 29.08)	28.34 (27.71 - 28.96)	-0.09 (-1.14 - 0.96)	-0.36[a] (-1.08 - 0.37)	-0.27 (-1.51 – 0.98)
SF-LLFDI disability limitation (DL), score 8-40 (SEMAI n=62, CALSTI n=86)					
Baseline	31.38 (30.50 - 32.26	31.67 (30.93 - 32.42)			
12 weeks	31.97 (30.85 - 33.09)	33.48 (32.68 - 34.28)	0.59 (-0.72 – 1.91)	1.81[#] (0.82 – 2.79)	1.22 (-0.42 – 2.85)
24 weeks	31.73 (30.63 - 32.83)	32.06 (31.10 - 33.02)	0.35 (-0.94 – 1.65)	0.39[a] (-0.73 – 1.51)	0.04 (-1.75 – 1.82)
SF-LLFDI function (FU), score 15-75 (SEMAI n=61, CALSTI n=99)					
Baseline	48.78 (47.38 – 50.18)	49.14 (48.05 – 50.24)			
12 weeks	50.23 (48.61 – 51.85)	53.68 (52.47 – 54.89)	1.45 (-0.46 – 3.36)	4.53[#] (3.10 – 5.96)	3.08* (0.71 – 5.46)
24 weeks	49.31 (47.66 – 50.96)	52.50 (51.29 – 53.70)	0.53 (-1.40 – 2.47)	3.35[#] (1.92 – 4.78)	2.82* (0.45 – 5.19)

Difficulty in IADL/ADL, score 0-20[b] (SEMAI n=70, CALSTI n=102)					
Baseline	3.53 (3.03 - 4.03)	3.50 (3.08 - 3.92)			
12 weeks	3.13 (2.57 - 3.69)	2.59 (2.15 - 3.03)	-0.40[€] (-1.11 – 0.32)	-0.91[#] (-1.48 - -0.34)	-0.51 (-1.41 – 0.39)
24 weeks	3.79 (3.23 - 4.35)	2.85 (2.40 - 3.31)	0.26 (-0.45 – 0.98)	-0.65[#] (-1.23 - -0.06)	-0.91[€] (-1.82 – 0.00)
Self-reported health state, EQ-health VAS 0 to 100 (CALSTI n=80, SEMAI n=48)					
Baseline	59.42 (56.30 - 62.53)	60.33 (57.93 - 62.73)			
12 weeks	62.29 (58.77- 65.80)	64.66 (62.15 - 67.16	2.87 (-1.30 – 7.04)	4.33[#] (1.30 – 7.36)	1.46 (-3.75 – 6.67)
24 weeks	60.99 (57.42 - 64.57)	62.33 (59.62 - 65.04)	1.58 (-2.62 – 5.78)	2.01 (-1.19 – 5.20)	0.43 (-5.03 – 5.89)

SPPB = Short Physical Performance Battery; SF-LLFDI = Short Form of the Late Life Function and Disability Index. (I)ADL = (Instrumental) Activities of Daily Living; EQ-health VAS = the EQ-5D Visual Analogue Scale for self-reporting health status

*Significant at p<0.05

[#]Significant at p<0.01

[€] Tendency at p<0.1

[a] Significant change from 12 to 24 weeks

[b] lower score = less disability

Secondary outcomes

The CALSTI group significantly improved disability limitation- and function domains of the SF-LLFDI (6% and 9%), ADL/IADL (29%) and EQ-VAS (7%) at week 12. After week 24, the SF-LLFDI-FU, and ADL/IADL levels remained higher than baseline, while SF-LLFDI-DL declined from week 12 to 24 (p<0.01, not displayed). No changes were found in the SEMAI group at any timepoint, and interaction effects between group and time were demonstrated only for the SF-LLFDI-FU at week 12. Table 2 displays an overview of all secondary results.

Discussion

The main finding of this pragmatic randomized study was that the 24-week intervention combining exercise with a multi-factorial self-management programme (CALSTI) led to a faster and

statistically and clinically superior increase in functional capacity compared to the self-management programme alone (SEMAI). The increase in CALSTI exceeded the 1-point threshold for substantially clinical meaningful changes in SPPB(46) after 12 and 24 weeks, whereas SEMAI exceeded the 0.5-point threshold for moderate meaningful changes only after 24 weeks. The improvement in the CALSTI group led to a follow-up SPPB-score >9 which is relevant because this cut point has previously shown predictive of home care service utilization in a similar Danish population(38). In addition, the CALSTI group improved self-report measures of ADL and IADL disability, and self-reported functional capacity after 12 weeks combined intervention, and despite some tendency of declines, most these self-reported improvements remained at week 24.
The EQ-health VAS baseline level of 60.0 corresponded a 16–17-point deficit compared to the national +75-year population-norms for men and women respectively. Approximately 25% of this gap was catched up at week 12 in CALSTI, however, at 24-week follow-up the improvement was no longer significant.

The main exercise component in CALSTI was a progressive power-type resistance training protocol that has proven highly effective for enhancing neuromuscular function, including gait speed, in controlled set-ups(35, 50). Despite the diversity of facilities, trainers, and equipment across sites in this study, changes in functional capacity were not inferior to those observed in earlier exercise-studies in community-dwelling older adults(43, 51). The external validity was increased by the unique recruitment strategy through a well-known and well-accepted nationally regulated pathway. This possibly allowed a broader reach, and more specific recruitment of the intended at-risk target group demonstrated by the high proportion of the screened subjects meeting the eligibility criteria (44%). Loss-to-follow up was associated with lower SPPB score in the CALSTI

group only, indicating that this exercise protocol may need more extensive tailoring (i.e., reduced number of exercises, intensity, volume) to lower the barriers for persons with more advanced functional decline.

Interestingly, improvements in functional capacity followed different patterns in CALSTI and SEMAI. CALSTI improved mainly during the intensive exercise phase (week 0-12), while in SEMAI there were improvements throughout the 24-week period in the SPPB. Possibly, the self-management programme enabled participants of both groups to initiate and maintain new PA-behaviours on their own. Several programme features may have contributed to the observed changes. First, the self-management programme used multiple behaviour change strategies that have previously been linked to higher PA-levels in older adults(8-11, 13, 14). Second, the programme was theoretically based on the HAPA framework for which the causal pathways have been empirically demonstrated(52), and theory-based PA interventions seems in general superior to increase PA(53). And third, the use of motivational interviewing principles for developing group norms to elicit a safe, respectful, and open-minded environment, may potentially have facilitated self-efficacy, social support, peer learning and role modelling.

The limitations in the study should be noted when interpreting the findings. Because this study was purposely embedded in nationally-regulated primary care service pathways, health care providers were not allowed to offer citizens a service of lower standard than normal care. Also, the providers wished to compare CALSTI to a structured and more intensive version of the PHV (existing service) that may potentially become regulated standard care in the future. This ruled out the inclusion of a passive control group, preventing final conclusions of whether the SMS-programme caused the improvements in the SEMAI group. The extra attention itself as well as

selection bias towards those with higher motivation and readiness for change may have contributed to some of the observed effects in both groups. On the other hand, this possibly led to more conservative effect sizes that may closer reflect the actual benefits of implementing the CALSTI intervention. Another limitation is the high number of participants, predominantly from the SEMAI group, who did not provide self-reported outcomes at any time point. The baseline battery of questionnaires was filled in after group allocation, potentially affecting participants' motivation to complete the entry, increasing the risk of selection bias and low statistical power to these outcomes. Consequently, the results from self-reported outcomes in the SEMAI group should be considered suggestive only, and we were unable to establish if the increases in SPPB performance carried over to improved self-rated functioning and disability. The considerable proportion of missingness (i.e., ≈40%, s-Table 3) in the primary outcome, SPPB, at follow-up in SEMAI, was taken into consideration by adding baseline-SPPB to the imputation- and analysis models. Moreover, several diagnostic procedures were undertaken to investigate the validity of the imputation approach including conducting sensitivity analyses based on observed data only (supplemental material S5). The results of this analysis were highly similar to the primary analysis on imputed data, and importantly, the two approaches did not result in any conflicting conclusions (table 2 and s-table 8).

Our study has several strengths. We used a pragmatic setup with involvement of key stakeholders in the development and implementation processes without compromising important aspects to methodological quality and reproducibility. We applied a novel approach, allowing participants to self-determine which barriers for PA they would turn to tackling (e.g., nutritional risk factors, loneliness, incontinence), thereby accounting for the multi-factorial and subjective nature of PA-

participation and prevention of late life disability. Finally, we showed strong effects on the primary functional capacity outcome, SPPB.

Conclusions and implications for preventive practice and future research

This study showed that a complex intervention combining exercise with a multi-factorial self-management programme embedded in nationally-regulated preventive practice led to a large short-term improvement in a key measure of functional capacity and predictor of disability, which was sustained for 12 weeks after the exercise component stopped. The current results provide evidence supporting the implementation of such complex intervention in routine preventive care for community-dwelling older adults. Although conclusive evidence was not established, the results also indicate that the multi-factorial self-management programme alone may be successfully introduced to older adults unable or unwilling to participate in group-based exercise, and potentially when exercise is not feasible due to lack of resources. Longitudinal research and cost-effectiveness analysis are needed to investigate if the effects of this complex intervention translate into reduced self-reported disability and ultimately, prolonged independent living, and reduced health care costs.

References

1. Eurostat; Persons performing physical activity outside working time by duration in a typical week, educational attainment level, sex and age. 2019.

2. Parra-Rizo MA, Sanchis-Soler G; Satisfaction with Life, Subjective Well-Being and Functional Skills in Active Older Adults Based on Their Level of Physical Activity Practice. *Int J Environ Res Public Health* 2020;**17**(4). doi: 10.3390/ijerph17041299.

3. Rantanen T, Guralnik JM, Sakari-Rantala R, et al.; Disability, physical activity, and muscle strength in older women: the Women's Health and Aging Study. *Arch Phys Med Rehabil* 1999;**80**(2):130-5. doi: 10.1016/s0003-9993(99)90109-0.

4. Cunningham C, R OS, Caserotti P, et al.; Consequences of physical inactivity in older adults: A systematic review of reviews and meta-analyses. *Scand J Med Sci Sports* 2020;**30**(5):816-827. doi: 10.1111/sms.13616.

5. World Health Organization; Integrated care for older people: guidelines on community-level interventions to manage declines in intrinsic capacity. 2017.

6. World Health Organization. *WHO guidelines on physical activity and sedentary behaviour.* Geneva: World Health Organization, 2020.

7. Zubala A, MacGillivray S, Frost H, et al.; Promotion of physical activity interventions for community dwelling older adults: A systematic review of reviews. *PLoS One* 2017;**12**(7):e0180902. doi: 10.1371/journal.pone.0180902.

8. Sansano-Nadal O, Giné-Garriga M, Brach JS, et al.; Exercise-Based Interventions to Enhance Long-Term Sustainability of Physical Activity in Older Adults: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. *Int J Environ Res Public Health* 2019;**16**(14). doi: 10.3390/ijerph16142527.

9. McMullan, II, Bunting BP, Blackburn NE, et al.; The Mediating Role of Self-Regulation and Self-Efficacy on Physical Activity Change in Community-Dwelling Older Adults (≥65 Years): An Experimental Cross-Lagged Analysis Using Data From SITLESS. *J Aging Phys Act* 2021:1-10. doi: 10.1123/japa.2020-0322.

10. Umstattd MR, Hallam J; Older adults' exercise behavior: roles of selected constructs of social-cognitive theory. *J Aging Phys Act* 2007;**15**(2):206-18. doi: 10.1123/japa.15.2.206.

11. Umstattd MR, Wilcox S, Saunders R, et al.; Self-regulation and physical activity: the relationship in older adults. *Am J Health Behav* 2008;**32**(2):115-24. doi: 10.5555/ajhb.2008.32.2.115.

12. Martín-Borràs C, Giné-Garriga M, Puig-Ribera A, et al.; A new model of exercise referral scheme in primary care: is the effect on adherence to physical activity sustainable in the long term? A 15-month randomised controlled trial. *BMJ Open* 2018;**8**(3):e017211. doi: 10.1136/bmjopen-2017-017211.

13. Biedenweg K, Meischke H, Bohl A, et al.; Understanding older adults' motivators and barriers to participating in organized programs supporting exercise behaviors. *J Prim Prev* 2014;**35**(1):1-11. doi: 10.1007/s10935-013-0331-2.

14. Killingback C, Tsofliou F, Clark C; Older people's adherence to community-based group exercise programmes: a multiple-case study. *BMC Public Health* 2017;**17**(1):115. doi: 10.1186/s12889-017-4049-6.

15. Jonkman NH, Del Panta V, Hoekstra T, et al.; Predicting Trajectories of Functional Decline in 60- to 70-Year-Old People. *Gerontology* 2018;**64**(3):212-221. doi: 10.1159/000485135.

16. den Ouden ME, Schuurmans MJ, Mueller-Schotte S, et al.; Domains contributing to disability in activities of daily living. *J Am Med Dir Assoc* 2013;**14**(1):18-24. doi: 10.1016/j.jamda.2012.08.014.

17. Gibney S, Doyle G; Self-rated health literacy is associated with exercise frequency among adults aged 50+ in Ireland. *European Journal of Public Health* 2017;**27**(4):755-761. doi: 10.1093/eurpub/ckx028.

18. Nygaard I, Girts T, Fultz NH, et al.; Is urinary incontinence a barrier to exercise in women? *Obstet Gynecol* 2005;**106**(2):307-14. doi: 10.1097/01.AOG.0000168455.39156.0f.

19. Schrempft S, Jackowska M, Hamer M, et al.; Associations between social isolation, loneliness, and objective physical activity in older men and women. *BMC Public Health* 2019;**19**(1):74. doi: 10.1186/s12889-019-6424-y.

20. Dansie EJ, Turk DC, Martin KR, et al.; Association of chronic widespread pain with objectively measured physical activity in adults: findings from the National Health and Nutrition Examination survey. *J Pain* 2014;**15**(5):507-15. doi: 10.1016/j.jpain.2014.01.489.

21. Jefferis BJ, Iliffe S, Kendrick D, et al.; How are falls and fear of falling associated with objectively measured physical activity in a cohort of community-dwelling older men? *BMC geriatrics* 2014;**14**:114-114. doi: 10.1186/1471-2318-14-114.

22. Moschny A, Platen P, Klaassen-Mielke R, et al.; Barriers to physical activity in older adults in Germany: a cross-sectional study. *Int J Behav Nutr Phys Act* 2011;**8**:121. doi: 10.1186/1479-5868-8-121.

23. European Regional Development Fund. *Interreg5a*. https://www.interreg5a.eu/en/ (Date Accessed 15 February 2022 Accessed, date last accessed)

24. Schulz KF, Altman DG, Moher D; CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *PLoS Med* 2010;**7**(3):e1000251. doi: 10.1371/journal.pmed.1000251.

25. Zwarenstein M, Treweek S, Gagnier JJ, et al.; Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *Bmj* 2008;**337**:a2390. doi: 10.1136/bmj.a2390.

26. Hoffmann TC, Glasziou PP, Boutron I, et al.; Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *Bmj* 2014;**348**:g1687. doi: 10.1136/bmj.g1687.

27. Andrade C; Internal, External, and Ecological Validity in Research Design, Conduct, and Evaluation. *Indian journal of psychological medicine* 2018;**40**(5):498-499. doi: 10.4103/IJPSYM.IJPSYM_334_18.

28. Act on Social Services no. 798 §79a. In: Ministry of Social Affairs and Senior Citizenss (ed). *https://www.retsinformation.dk/eli/lta/2021/1548*, 2021.

29. Danish Health Authority. *Forebyggende hjemmebesøg til ældre - vejledning. [Preventive home-visits for older adults - a guideline]*, 2020.

30. World Health Organization. *International classification of functioning, disability and health: ICF.* Geneva: World Health Organization, 2001.

31. Cooper R, Popham M, Santanasto AJ, et al.; Are BMI and inflammatory markers independently associated with physical fatigability in old age? *Int J Obes (Lond)* 2018. doi: 10.1038/s41366-018-0087-0.

32. Cleeland CS, Ryan K; The brief pain inventory. *Pain Research Group* 1991.

33. Vasunilashorn S, Coppin AK, Patel KV, et al.; Use of the Short Physical Performance Battery Score to predict loss of ability to walk 400 meters: analysis from the InCHIANTI study. *J Gerontol A Biol Sci Med Sci* 2009;**64**(2):223-9. doi: 10.1093/gerona/gln022.

34. Vaarst J, Boyle E, Vestergaard S, et al.; Does physical performance and muscle strength predict future personal and nursing care services in community-dwelling older adults aged 75+? *Scand J Public Health* 2021:1403494820979094. doi: 10.1177/1403494820979094.

35. Caserotti P, Aagaard P, Larsen JB, et al.; Explosive heavy-resistance training in old and very old adults: changes in rapid muscle force, strength and power. *Scand J Med Sci Sports* 2008;**18**(6):773-82. doi: 10.1111/j.1600-0838.2007.00732.x.

36. Lorig KR, Holman H; Self-management education: history, definition, outcomes, and mechanisms. *Ann Behav Med* 2003;**26**(1):1-7. doi: 10.1207/s15324796abm2601_01.

37. Bandura A. *Self-efficacy: The exercise of control.* New York: W. H. Freeman, 1997.

38. Schwarzer R; Social-Cognitive Factors in Changing Health-Related Behaviors. *Current directions in psychological science : a journal of the American Psychological Society* 2016;**10**(2):47-51. doi: 10.1111/1467-8721.00112.

39. Miller WR, Rollnick S. *Motivational interviewing: helping people change.* New York, NY: Guilford Press, 2013.

40. Schwarzer R; Modeling Health Behavior Change: How to Predict and Modify the Adoption and Maintenance of Health Behaviors. *Applied psychology* 2008;**57**(1):1-29. doi: 10.1111/j.1464-0597.2007.00325.x.

41. Schwarzer R. *the Health Action Process Approach*. http://www.hapa-model.de/ (Date Accessed February 15, 2022 Accessed, date last accessed)

42. Guralnik JM, Simonsick EM, Ferrucci L, et al.; A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *Journal of gerontology (Kirkwood)* 1994;**49**(2):M85-M94. doi: 10.1093/geronj/49.2.M85.

43. Pahor M, Blair SN, Espeland M, et al.; Effects of a physical activity intervention on measures of physical performance: Results of the lifestyle interventions and independence for Elders Pilot (LIFE-P) study. *J Gerontol A Biol Sci Med Sci* 2006;**61**(11):1157-65. doi: 10.1093/gerona/61.11.1157.

44. Guralnik JM, Ferrucci L, Simonsick EM, et al.; Lower-Extremity Function in Persons over the Age of 70 Years as a Predictor of Subsequent Disability. *The New England Journal of Medicine* 1995;**332**(9):556-562. doi: 10.1056/NEJM199503023320902.

45. Pavasini R, Guralnik J, Brown JC, et al.; Short Physical Performance Battery and all-cause mortality: systematic review and meta-analysis. *BMC Med* 2016;**14**(1):215. doi: 10.1186/s12916-016-0763-7.

46. Perera S, Mody SH, Woodman RC, et al.; Meaningful change and responsiveness in common physical performance measures in older adults. *J Am Geriatr Soc* 2006;**54**(5):743-9. doi: 10.1111/j.1532-5415.2006.00701.x.

47. Saliba D, Orlando M, Wenger NS, et al.; Identifying a short functional disability screen for older persons. *J Gerontol A Biol Sci Med Sci* 2000;**55**(12):M750-6. doi: 10.1093/gerona/55.12.m750.

48. McAuley E, Konopack JF, Motl RW, et al.; Measuring disability and function in older women: psychometric properties of the late-life function and disability instrument. *J Gerontol A Biol Sci Med Sci* 2005;**60**(7):901-9. doi: 10.1093/gerona/60.7.901.

49. EuroQol Research Foundation; EQ-5D-3L User Guide. 2018.

50. Hvid LG, Strotmeyer ES, Skjødt M, et al.; Voluntary muscle activation improves with power training and is associated with changes in gait speed in mobility-limited older adults - A randomized controlled trial. *Exp Gerontol* 2016;**80**:51-6. doi: 10.1016/j.exger.2016.03.018.

51. Zhang Y, Zhang Y, Du S, et al.; Exercise interventions for improving physical function, daily living activities and quality of life in community-dwelling frail older adults: A systematic review and meta-analysis of randomized controlled trials. *Geriatr Nurs* 2020;**41**(3):261-273. doi: 10.1016/j.gerinurse.2019.10.006.

52. Zhang C-Q, Zhang R, Schwarzer R, et al.; A meta-analysis of the health action process approach. *Health psychology* 2019;**38**(7):623-637. doi: 10.1037/hea0000728.

53. Chase JA; Interventions to Increase Physical Activity Among Older Adults: A Meta-Analysis. *Gerontologist* 2015;**55**(4):706-18. doi: 10.1093/geront/gnu090.