Effects of a physical and nutritional intervention program for frail elderly people over age 75. A randomized controlled pilot treatment trial

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ABSTRACT. Background and aims: There are few studies published that combine the interventions of physical training and nutrition. The aim of the present study was to describe the impact of a physical and nutritional intervention program for frail community-dwelling elderly people over the age of 75. Methods: Ninety-six community-dwelling elderly people (58 women) were randomized to four different groups: i) a physical training program (aerobic, muscle strength, balance), ii) a nutritional intervention program (individually targeted advice and group sessions), iii) a combination of these interventions, and iv) a control group. At baseline subjects were screened for physical performance such as muscle strength, balance, mobility and activities of daily living, as well as nutritional aspects such as energy intake, body weight and fat-free mass. These measurements were repeated immediately after the intervention, which lasted for 12 weeks, and after another 6 months. Results: The intention-to-treat analysis indicated significant improvements in lower-extremity muscle strength in both training groups compared with the nutrition group at 1st follow-up. There were small significant changes for some of the balance measurements in the training group without nutrition treatment. The nutrition intervention did not show any significant results. Conclusions: This study shows the positive effect on lower-extremity muscle strength directly after the intervention. Balance training most probably needs to be more individualized in order to be effective for frail elderly people. Further studies are needed, with larger sample sizes, to investigate the effects of these types of interventions before any further conclusions can be drawn.

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INTRODUCTION

It has been suggested that frailty as a physical state (intrinsic frailty) should be distinguished from the consequences of frailty. Intrinsic frailty is based on such impairments as unintentional weight loss, impaired muscle strength, balance and mobility, as well as low physical activity level. The consequences of frailty are changes in functional independence, psychosocial factors (e.g., emotions, self-efficacy and role function) and health care consumption (1-3).

There are only a few published randomized controlled trials (RCT) that focus on both nutrition and physical function in frail elderly people (4-7). A positive energy balance seems to have a positive effect on body weight and possibly on body composition (4-6). Physical training can improve both muscle strength and integrated physical functions such as gait velocity and stair-climbing power, and the overall level of physical activity (4, 5, 7). However, there seems to be a limited combined effect of nutrition and physical training (4-7).

None of the studies cited above (4-7) combined aerobic training and balance training with high-intensity muscle strength training. Moreover, individualized nutritional treatment was not part of the intervention.

Knowledge of individual compliance to the treatment program is vital to be able to draw conclusions from a clinical study (8). Several factors have been shown to affect compliance for physical training in elderly people, such as self-efficacy, social support and barriers (9, 10). Different

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theoretical models for lifestyle changes have been developed. For example, the Health Belief Model includes barriers, benefits, self-efficacy and social support (11).

The primary aim of the present study was to describe the impact of a physical and nutritional intervention program for frail community-dwelling elderly people. A secondary aim was to describe the differences between subjects who improved and those who did not, and between compliers and non-compliers.

MATERIAL AND METHODS

Subjects

In June 2002, a questionnaire regarding self-rated nutritional health and physical activity level was sent to all 6197 individuals over age 75 in the city of Solna, Sweden.

An advertisement was published in the local newspaper in May 2003, and primary care organizations were contacted during the same period.

In January 2004, an invitation letter was sent to all people over age 75 (n=794) receiving home services in the municipality of Solna.

Inclusion criteria were: a) unintentional weight loss ≥5% and/or body mass index (BMI) ≤20 kg/m^2; and b) low physical activity level (≤ grade 3 on a six-graded scale of physical activity (12, 13)).

Exclusion criteria were age under 75, BMI >30 kg/m^2, non-walkers, people with recent cardiac problems requiring hospital care, recent hip fracture or surgery

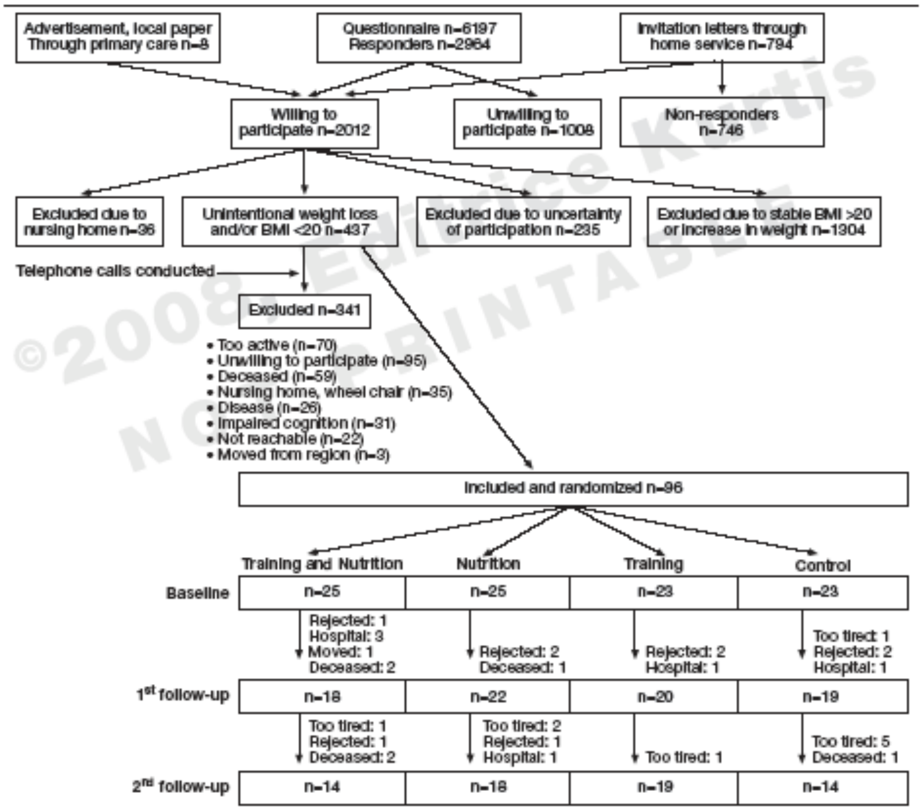

Fig. 1 - *Flow of recruitment, inclusion/exclusion and drop-out of subjects from baseline to 2nd follow-up.*

during the last six months, present cancer treatment, stroke within the last two years, less than 7 points of a total 9-point score on the short form of the Mini Mental State Examination (14), and institutionalization.

Figure 1 shows detailed information concerning successive recruitment of subjects and drop-outs. All subjects (n=437) who fulfilled the inclusion criteria regarding unintentional weight loss and/or BMI ≤20 kg/m^2 were contacted by telephone for screening. A final sample of 96 subjects was included in the study; however, three subjects were excluded from the nutritional analyses due to missing data on energy intake.

Procedure

Subjects were randomized consecutively in batches into four different groups. The randomization procedure was conducted in an open manner by the study personnel, instructed by a statistician. For each new group included, randomization started with the oldest individual, to avoid age differences between groups.

Randomization was carried out for the following treatment groups:

1. Nutrition (N) (n=25): Specific individualized diet counseling and group session education, plus general physical training advice;
2. Training (T) (n=23): Specific physical training, plus general diet advice;
3. Training and nutrition (T+N) (n=25): Specific physical training, plus specific individualized diet counseling and group session education;
4. Control (C) (n=23): General physical training advice and general diet advice.

Subjects were assessed at baseline (0 months), 1st follow-up (3 months) and 2nd follow-up (9 months, i.e., 6 months after end of intervention).

The study was approved by the Ethical committee at the Karolinska Institutet. All subjects were informed about the study procedures and they gave written informed consent for participation.

Baseline characteristics

Subjects were examined by a geriatrician for medical history, medication and physical status. Education and type of walking aids were recorded. Physical activity level was estimated according to a six-graded ordinal scale, including both physical training/exercises and household activities (12, 13).

Outcome measures

Physical performance

Muscle strength was measured in the lower extremities with combined knee and hip extension (Leg press Scandinavian Mobility), and in the upper extremity with elbow extension (Dips, Scandinavian Mobility) and shoulder extension (Pull-down, Scandinavian Mobility) with one repetition maximum (1RM) (15, 16). 1RM was performed in the individual full range of motion after a warm-up session. Subjects performed two repetitions in the full range of motion on each load until the maximum load was achieved. The procedure was conducted according to the recommendations of the American College of Sports Medicine (17). During leg press measurement, subjects were instructed to hold on to bars next to the seat. During measurements in dips and pull-down, a footstool was used to ensure sitting stability, if needed.

A 30-second chair-stand test was conducted and the number of stands was recorded (18). Subjects were instructed to rise from a chair (height 44 cm) with their arms folded over their chest, as many times as possible in 30 sec. They were instructed to stand fully erect and sit down properly each time.

The number of step-ups in 30 seconds with or without support was recorded. Subjects were instructed to step up with both feet to a standing position on a 15-cm block and then down again, alternating left and right starting foot. The type of support was self-selected by subjects and was recorded.

Balance, defined as maintenance of postural control, was measured with tandem stance (TS) and one-leg stance (OLS) (19, 20). Subjects were allowed 1-2 trials before time-keeping started. Time-keeping ended if the subject's foot/feet changed position or after 30 seconds. Subjects were instructed to wear comfortable shoes, and arm position was self-selected. In both TS and OLS, the preferred leg was used and recorded at baseline. The same leg was then tested at follow-ups.

The Modified Figure Eight (MFE), in which subjects walk in a figure of eight, on two 4-cm wide circles with an inner diameter of 163 cm, was measured (21). Subjects were instructed to walk with both feet on the line if possible, at a self-selected speed (22). The number of complete steps outside the line was recorded.

Another measurement of balance, the step test, was also used (23). Subjects were instructed to place the whole foot on to a 15-cm high block and down again, alternating left and right foot during 30 seconds. This was conducted without support, and the number of steps was recorded.

Timed Up and Go (TUG) and TUG manual were measured (20, 24, 25). The subjects were instructed to rise from a chair (height 44 cm), walk three meters, turn around at a mark on the floor, and walk back to be seated again. This activity was timed. Subjects were allowed to use their usual walking aids. This procedure was conducted twice with (TUG manual) and without (TUG) carrying a tumbler of water.

Walking speed was measured indoors with timed 10-meter walk tests at maximal walking speed (adding one meter for acceleration and deceleration respectively) (26). Subjects were allowed to use their usual walking aids.

Personal activities of daily living (PADL) were estimated by the test leader using the Functional Independence Measure (FIM) (27, 28). This ordinal scale consists of a 13-item (motor items), 7-graded scale, a maximum of 91 points indicating independence.

Instrumental activities of daily living (IADL) were estimated by the test leader using the Instrumental Activity Measures (IAM), a supplementary scale to FIM (29, 30). This ordinal scale consists of an 8-item (e.g. cleaning, washing clothes, cooking, food purchasing, transport, etc.), 7-graded scale, a maximum of 56 points indicating independence.

The same test leader conducted all physical performance measurements on all occasions. A handheld stopwatch was used for all time-keeping measurements.

Nutritional measures

Body composition was measured by weighing the subjects, in their underwear, to the nearest 0.1 kg on a digital chair scale (UMEDICO SV-600, Rosersberg, Sweden). Height was measured to the nearest centimeter using a wall-mounted stadiometer. Four skin folds were measured using a Harpenden calliper (British Indicators Ltd, Bedfordshire, UK) (31) over biceps, triceps, subscapular and crista iliac, using the mean of three measurements to the nearest 0.1 mm from each location. Fat mass was calculated from the sum of these four skin folds using prediction equations (32, 33). Fat-free mass (FFM) was calculated as body weight minus fat mass.

BMI was calculated by dividing body weight (kg) by height^2 (m).

Energy intake was analyzed with a four-day food record, in which the subjects reported all foods eaten. At a home visit, the nutritionist/dietician went through the record, verifying details on foods used as well as measures and portion sizes. Food intake data were computerized, and energy content was calculated by StorMATS (version 4.06, 2002, Rudans Lättdata, Västerås, Sweden) and the Swedish national nutrient database, PC-kost (version 02_1, National Food Administration, 2002). All measurements of energy intake were expressed as kcal per kg body weight. Missing values in the database were queried on the producers' websites and, when available, entered into the program; otherwise similar products were chosen.

Health Belief Model

Dimensions suggested for inclusion in the Health Belief Model are barriers, benefits, self-efficacy and social support (11).

These dimensions were put into four different statements: barriers - "*I have great difficulty in changing my physical activity level*"; benefits - "*I can see major advantages in changing my physical activity level*"; self-efficacy - "*I have great confidence in my ability to change my physical activity level*" and social support - "*I have extensive social support for changing my physical activity level*". An overall statement "*I am highly motivated to perform physical activities regularly*", was also used.

These statements were given a rating on a scale from 1 to 10, where 1 equals "definitely false" and 10 equals "definitely true", except for the statement "*I have great difficulty …*" where 1 equals "definitely true" and 10 equals "definitely false".

The statements were estimated twice at baseline approximately one week apart by means of face-to-face interviews, and showed a significant but moderate test re-test reliability of r=0.46 for barriers, r=0.33 for benefits, r=0.66 for self-efficacy, r=0.66 for social support and r=0.64 for the overall statement. It was also administered at 1st and 2nd follow-up.

Intervention

Physical training

Subjects randomized to the physical training program participated in an organized regular physical group training program of approximately one hour, twice a week for 12 weeks.

The program consisted of three corresponding sections: warm-up, including aerobic training; individually prescribed muscle-strength training (60-80% intensity); and Qigong, including cool-down, performed in groups of 5-8 subjects. After each section, subjects were asked to score their effort on the CR-10 scale according to Borg (34), and heart rate was recorded.

The warm-up/aerobic training section consisted of standing exercises, such as walking/jogging on the spot, walking forwards/backwards and sideways, and arm movements. Arm and leg exercises were performed separately, to increase the intensity rather than the difficulty in coordination. The 20-minute section also consisted of a short cool-down period halfway, for range-of-motion activities and stretching. Subjects were allowed to use their ordinary walking aids if needed.

The 20-minute muscle-strength training section consisted of two separate stations: strength training on stationary equipment and functional strength training.

During the first two weeks, most of the subjects performed at 60% intensity, with repetition 1x8 on stationary equipment (leg press, dips, and pull-down, see Physical performance above). In the 3rd week, intensity was increased to 80% of 1RM. At the 6th and 10th weeks, the 1RM procedure was repeated to ensure 80% intensity. Two subjects started the training program on the stationary equipment at 50%, increasing to 70%, due to diseases such as post polio syndrome and myasthenia gravis.

The functional strength training station consisted of chair stand, step-up and toe raise. According to their baseline values, subjects performed the exercises with or without a weight belt. If possible, the amount of kilograms added was 10% of subjects' individual initial body weight. This was increased during the 12 weeks up to 20% of

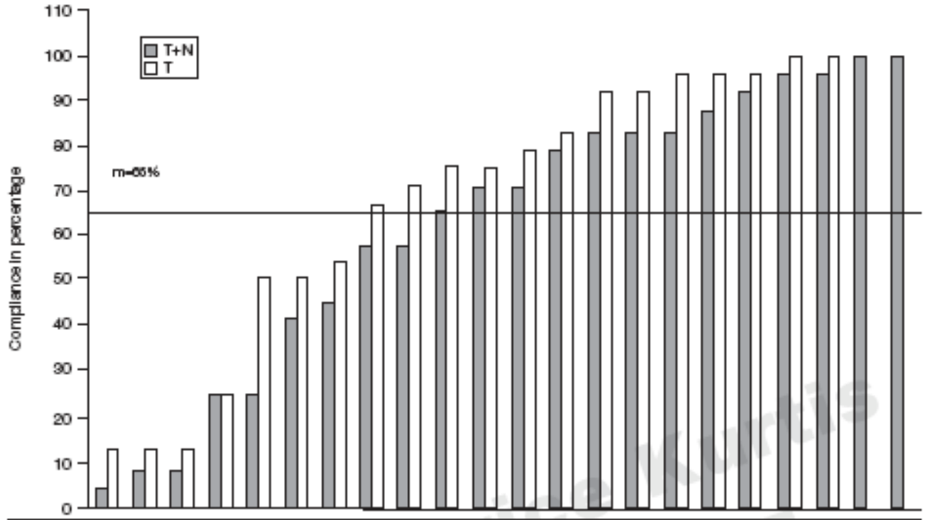

Fig. 2 - *Compliance rate (%) during 12-week physical training program. Horizontal line: mean level of compliance.*

body weight, according to subjects' abilities and scored effort. These exercises were repeated 2x10. Subjects who could not perform one chair stand from a chair (height 44 cm) performed the exercise from a bunk, adjustable to different heights in a vertical position; progressed by lowering the height of the bunk or by switching to a chair.

The balance training section consisted of various Qigong exercises performed on different degrees of supporting area, combined with arm and trunk movements. These exercises progressed with increasing difficulty. Subjects were encouraged to stand without support during all these exercises. Those with poor balance stood in front of a chair or bunk and had their walker in front of them to create safe surroundings. The exercises ended with a short cool-down period.

The mean compliance rate was 65% (4-100%). The results of compliance, scoring of effort, percentage of predicted heart rate recording (220 minus age) and progress of muscle-strength training are shown in Figures 2-5.

The training program was planned by a physiotherapist and led by a trained instructor with the help of a trained physiotherapy assistant.

The trained instructor was not involved in assessments of outcome measures. The trained physiotherapy assistant helped the instructor with recording of heart rate and scored effort, and ensured correct load and safety during balance training, etc.

Nutritional treatment

Nutritional treatment consisted of individual dietary counseling, which was based on baseline food record data. Using the results of the food record, the dietician/nutritionist tested different options that would cover the estimated needs of each individual, and then gave advice on food intake at an individual session lasting about one hour. The results of the baseline tests were explained, and changes in daily eating patterns and food choices were suggested and discussed. Nutritional

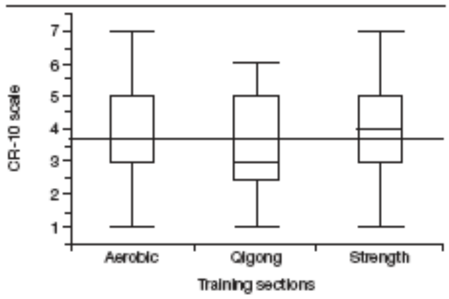

Fig. 3 - *Estimated scored effort (median, quartiles and range) during three different sections of physical training program.*

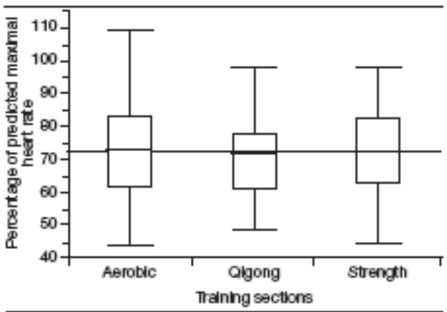

Fig. 4 - *Level of predicted maximal heart rate (220 minus age) (median, quartiles and range) during different sections of physical training program.*

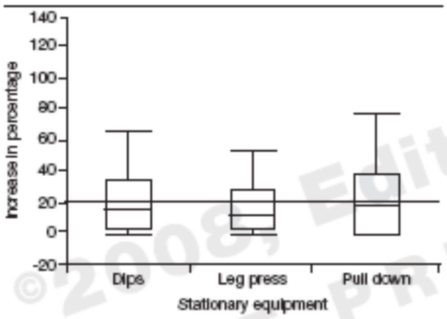

Fig. 5 - *Level of increase in muscle strength training load (%) (median, quartiles and range) on stationary equipment.*

treatment included five group sessions, covering such topics as the nutritional needs of elderly people, meal frequency and cooking methods. At each session, an example of a nutritionally well-balanced between-meal snack was served.

Forty-six out of 49 eligible subjects (one was excluded due to missing data on energy intake) completed individual dietary counseling, and the mean compliance rate for the N and T+N groups during group sessions was 73% (20-100%).

General advice

The general physical training advice for the control group was to walk three times per week for at least 20 minutes, to use staircases instead of an elevator from time to time, and to follow WHO recommendation of a total amount of 30 minutes of physical activity/day.

The general diet advice was to eat three main courses and 2-3 between-meal snacks including meat, fish or egg, fruit and vegetables, dairy products and fiber, in combination with fluid every day.

Statistical methods

Statistical analysis was conducted in JMP 6.0.0 (SAS Institute, USA). Continuous data is presented as means (m) and standard deviations (sd), and ordinal data and continuous data with "ceiling effect" as medians (md) and first and third quartiles (q1-q3).

Scatter-plots for baseline variables against change in outcome variables were used to investigate whether baseline values had any impact on the magnitude of change. No consistent patterns were noted, and baseline values were therefore not used as covariates in the analysis.

Between-group analyses were conducted with an intention-to-treat analysis, including all subjects regardless of compliance, by one-way ANOVA and the Tukey-Kramer HSD as *post-hoc* tests for continuous data with normal distribution and Wilcoxon/Kruskal-Wallis tests for ordinal data and continuous data with skewed distribution. Within-group analyses were conducted with the Matched Paired *t*-test for continuous data and the Wilcoxon Sign test was used for ordinal data and continuous data with skewed distribution.

Subjects were regarded as improvers if they had a positive difference between baseline and 1st follow-up, and as non-improvers if there was no change or a negative difference. Compliance was regarded as either a continuous variable or dichotomized, in which subjects were regarded as compliers if they had attended >65% of the training sessions. Analyses of improvers/non-improvers and compliers/non-compliers were conducted with Student's *t*-test for continuous data, Wilcoxon Kruskal-Wallis tests for ordinal data and Fisher's Exact Test for nominal data.

RESULTS

Baseline characteristics

Table 1 shows the baseline characteristics and baseline values of outcome variables for physical performance and nutritional measures. The C group had significantly more subjects with high school and/or university degrees compared with the N group. The C and N group estimated their physical activity level higher last winter compared with the T+N and T groups. For further comparison see Table 1.

The groups were comparable at baseline concerning physical performance except for FIM in which the N and C groups had significantly higher values compared with the T+N group (Table 1).

Effects of intervention

Physical performance

Between-group analyses showed that there was a significant improvement regarding leg press, dips and step tests: i) leg press for the T+N and T groups compared with the N group at 1st follow-up, with mean differences of 11.4 kg [CI 95% 0.8 ; 21.9] and 14.3 kg [4.4 ; 24.1] respectively ($p<0.01$) (see Fig. 6); ii) dips for the T+N and T groups compared with the C group at 1st follow-up, with mean differences of 2.9 kg [0.2 ; 5.5] and 3 kg [0.4 ; 5.5] respectively ($p<0.01$); iii) step test for the T group compared with the T+N group with a mean difference of 4.3 [0.2 ; 8.5] ($p<0.05$).

There were no significant between-group differences between baseline and 2nd follow-up.

Within-group analyses are shown in Table 2. Significant positive differences were mainly observed for muscle strength measurements in the T and T+N groups, and are marked gray in the columns. There were no significant differences for FIM and IAM within groups (data not shown).

Nutritional measures

There were no significant differences between groups, but there was a significant but small decrease in FFM within the T group between baseline and 2nd follow-up (see Table 2).

Table 1 - *Baseline characteristics and baseline values of outcome variables for physical performance and nutritional measures. Significant differences are shown in gray.*

	N group (n=25)	T group (n=23)	T+N group (n=25)	C group (n=23)
Age (m)	83.1 (4.5)	83.5 (3.7)	83.1 (4)	82.9 (4)
Gender	M=10, W=15	M=12, W=11	M=9, W=16	M=7, W=16
Continuous medications (m)	7 (4)	6 (3)	6 (3)	6 (3)
Education (n)				
secondary school or lower	20	16	19	12
high school or higher	5	7	5	11*
Body mass index (m)	21.8 (3.4)	21.9 (3.8)	21.9 (3.4)	21.6 (3.6)
Physical activity level (md)				
last summer	2 (2-3) (n=16)¤	2 (2-3) (n=15)	2 (1-3) (n=20)	3 (2-3) (n=18)
last winter	2 (2-3)¤§	2 (2-2) (n=20)	2 (1-3)	3 (2-3)¤§
Walking aids outdoors (n)				
no aid	14¤	8	4	11¤
stick	5	5	7	2
walker	6¤	10	13	10
Walking aids indoors (n)				
no aid	21	17	15	18
stick	3	4	4	2
walker	1¤	2	5	3
Muscle strength (m)				
leg press (kg)	76 (27.8)	71 (19.8)	70 (20.8)	78 (26.4)
dips (kg)	16 (6.6)	18 (6.9)	16 (7)	17 (7.4)
pull-down (kg)	23 (8.7)	22 (8.6)	23 (6.6)	23 (9)
Functional muscle strength (m)				
chair-stand (number)	6 (4)	6 (3.9)	5 (3.9)	7 (5)
step-ups (number)	7 (2.1)	6 (2)	7 (2.3)	7 (2.2)
Balance (m, md)				
tandem stance (sec)	1.9 (0-7.5)	2.5 (0-26.5)	2 (0-10.8)	5.6 (0-19.8)
one leg stance (sec)	3.1 (1.7-5.9)	2.8 (1-11)	2.2 (1.1-4.3)	3.1 (2.3-6.8)
modified figure eight (step)	16 (12.4)	16 (17.2)	21 (18.1)	14 (12.4)
step test (number)	12 (7.3)	11 (7.3)	13 (8)	13 (8.7)
Mobility (m)				
TUG (sec)	14 (4.2)	18 (10.3)	15 (4.2)	13 (5.1)
TUG manual (sec)	16 (5.1)	18 (7.6)	16 (4.4)	15 (6.1)
maximal walking speed (m/s)	1.3 (0.4)	1.1 (0.4)	1.2 (0.3)	1.3 (0.4)
Activities of daily living (md)				
FIM	88 (86-89)¤	88 (83-89)	84 (81-88)	88 (83-90)¤
IAM	45 (39-49)	38 (31-43)	42 (28-48)	43 (37-48)
Nutritional measures (m)				
body weight (kg)	60 (10)	58 (11)	60 (12)	58 (10)
fat free mass (kg)	43 (8)	44 (8)	43 (9)	42 (8)
energy intake (kcal/kg body weight)	28 (9)	25 (7)	27 (8)	28 (8)

n: number; m: mean (sd), md: median. M: men; W: women; TUG: Timed Up and Go; FIM: functional independence measure; IAM: instrumental independence measure. *significant difference compared with N group; ¤significant difference compared with T+N group; §significant difference compared with T group. $p<0.05$.

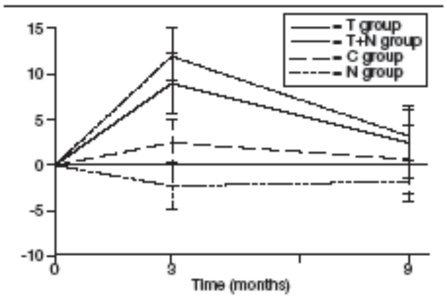

Fig. 6 - *Mean differences (SEM) for Leg press between baseline (0 months) and 1st and 2nd follow-up (3 and 9 months) for four groups, respectively. Significant increase for T and T+N groups compared with N group (p<0.01).*

Health Belief Model

Table 3 shows the results of the estimated ratings of the different statements, both *between-group* analyses at baseline and *within-group* analyses between baseline and follow-ups. The groups were comparable at baseline except for benefits and self-efficacy.

There were no differences between groups regarding statements between baseline and follow-ups.

Within-group analyses showed that N group significantly increased its estimated ratings for benefits, and T group for self-efficacy between baseline and 1st follow-up. The T+N group significantly increased its estimated ratings of the overall statement "*I am highly motivated …*" between baseline and 1st follow-up. There were no within-group differences between baseline and 2nd follow-up.

Table 2 - *Results of intention-to-treat within-group analyses showing differences between baseline and 1st (F1) and 2nd (F2) follow-ups, respectively. Significant differences are shown in gray.*

	Follow-up	Dif. Mean (CI 95%)			
		N	T	T+N	C
Muscle strength					
Leg press (kg)	F1	-2.4 (-7.9 ; 3.2)	11.9 (6.3 ; 17.5)***	9 (1.8 ; 16.2)*	2.4 (-2.9 ; 7.7)
	F2	-1.8 (-7 ; 3.4)	3.3 (-2.8 ; 9.4)	2.4 (-6.3 ; 11.2)	0.5 (-7.9 ; 9)
Dips (kg)	F1	-0.2 (-1.1 ; 0.7)	1.8 (0.8 ; 2.8)**	1.7 (0.04 ; 3.4)*	-1.1 (-3.2 ; 0.9)
	F2	-1.1 (-2.7 ; 0.4)	0.06 (-0.7 ; 0.9)	1 (-0.7 ; 2.7)	-2.1 (-4.9 ; 0.7)
Pull-down (kg)	F1	0.5 (-0.4 ; 1.3)	3.4 (0.9 ; 5.8)**	2 (-0.2 ; 4.2)	0.4 (-2.1 ; 2.8)
	F2	0.6 (-1.1 ; 2.3)	2.7 (0.9 ; 4.6)**	0 (-1.7 ; 1.7)	-0.4 (-3.8 ; 3)
Chair stand (number)	F1	0.6 (0.05 ; 1.1)*	1 (0.004 ; 2)*	1.2 (0.07 ; 2.3)*	-0.2 (-0.9 ; 0.6)
	F2	0 (-1.1 ; 1.1)	0.2 (-1 ; 1.4)	0.4 (-1 ; 1.8)	-0.07 (-1.1 ; 1)
Step-ups (number)	F1	-0.2 (-0.7 ; 0.2)	2.2 (1.1 ; 3.3)***	0.8 (-0.3 ; 1.9)	0.6 (-0.1 ; 1.3)
	F2	0 (-0.7 ; 0.7)	1.1 (0.3 ; 1.8)**	1 (-0.4 ; 2.4)	-0.6 (-2.2 ; 1.1)
Balance					
Tandem stance (sec)	F1	2.6 (-2 ; 7.2)	1.9 (-0.2 ; 4.1)	-4.3 (-9.3 ; 0.6)	-0.09 (-3.7 ; 3.5)
	F2	-5 (-9.7 ; -0.2)	-2.4 (-4.4 ; -0.5)	-4.9 (-10.9 ; 1)	-7.5 (-15.3 ; 0.3)
One leg stance (sec)	F1	0.9 (-1 ; 2.8)	1.3 (-0.5 ; 3)	-0.003 (-2.6 ; 2.5)	1.7 (-1.6 ; 4.9)
	F2	-1.4 (-3 ; 0.04)	-0.2 (-3.7 ; 3.3)	-1 (-4.1 ; 2.1)	1.1 (-3 ; 5.1)
Modified figure eight (step)	F1	0.9 (-3.3 ; 5)	-4.3 (-7.8 ; -0.8)*	-0.2 (-6.3 ; 5.8)	0.7 (-1.3 ; 2.6)
	F2	3.4 (-3.2 ; 10)	1.5 (-2.9 ; 6)	-0.2 (-9.7 ; 9.4)	1.2 (-3.7 ; 6)
Step test (number)	F1	0.2 (-1.8 ; 2.2)	3.2 (0.9 ; 5.5)**	-1.1 (-3.2 ; 1)	0.05 (-2.8 ; 2.7)
	F2	0.3 (-2.1 ; 2.7)	1.1 (-1.4 ; 3.6)	-0.9 (-4 ; 2.2)	-0.6 (-5.2 ; 4.1)
Mobility					
TUG (sec)	F1	-0.2 (-1.4 ; 0.9)	-2.6 (-6.1 ; 0.9)	0 (-1.7 ; 1.7)	-0.06 (-0.8 ; 0.7)
	F2	0.06 (-1.9 ; 2)	-2.1 (-5.7 ; 1.5)	0.3 (-2.2 ; 2.8)	3.9 (-4.2 ; 11.9)
TUG manual (sec)	F1	-0.4 (-2.2 ; 1.4)	-2 (-4.5 ; 0.5)	1.4 (-0.6 ; 3.4)	0.7 (-0.4 ; 1.9)
	F2	0.6 (-1.8 ; 3)	-1.1 (-4.3 ; 2.2)	0.4 (-2.8 ; 3.6)	1.08 (-0.6 ; 2.7)
Maximal walking speed (m/s)	F1	-0.01 (-0.1 ; 0.1)	0.05 (-0.05 ; 0.1)	0.006 (-0.07 ; 0.08)	0.03 (-0.04 ; 0.1)
	F2	0.03 (-0.07 ; 0.1)	0.02 (-0.07 ; 0.1)	-0.07 (-0.3 ; 0.1)	-0.09 (-0.3 ; 0.1)
Nutritional measures (m)					
Body weight (kg)	F1	0.8 (-0.2 ; 1.7)	-0.1 (-0.9 ; 0.7)	-0.3 (-1.2 ; 0.7)	0.6 (-0.6 ; 1.8)
	F2	2.2 (-0.1 ; 4.5)	-0.7 (-1.9 ; 0.4)	0.2 (-1.7 ; 2.2)	0.5 (-0.6 ; 1.5)
Fat free mass (kg)	F1	0.7 (-0.01 ; 1.5)	-0.4 (-1.1 ; 0.3)	0.2 (-0.3 ; 0.8)	0.3 (-0.6 ; 1.2)
	F2	-0.2 (-1.5 ; 1)	-0.9 (-1.7 ; -0.2)*	-0.1 (-1.3 ; 1.1)	0.2 (-0.9 ; 1.3)
Energy intake (kcal/kg body weight)	F1	0.6 (-2.3 ; 3.6)	1.6 (-1 ; 4.2)	0.3 (-2.9 ; 3.5)	-0.6 (-4.3 ; 3.3)
	F2	2.2 (-0.1 ; 4.5)	-0.4 (-3.9 ; 3.1)	1.8 (-1.8 ; 5.3)	0.1 (-6.4 ; 6.5)

*$p<0.05$; **$p<0.01$; ***$p<0.001$. TUG: Timed Up and Go.

Table 3 - *Description of results of ratings of different statements in Health Brief Model at baseline (B) and 1st (F1) and 2nd (F2) follow-ups for each group. md= median (q1-q3). Significant differences are shown in gray.*

	N group			T group			T+N group			C group		
	B (n=25)	F1 (n=22)	F2 (n=17)	B (n=23)	F1 (n=20)	F2 (n=19)	B (n=25)	F1 (n=18)	F2 (n=13)	B (n=23)	F1 (n=19)	F2 (n=14)
Health Belief Model												
Barriers (md)	4 (2-6)	5 (3-7)	4 (3-8)	4 (2-5)	5 (3-6)	4 (2-5)	4 (2-5)	4 (3-5)	4 (3-7)	5 (3-6)	5 (3-6)	5 (3-7)
Benefits (md)	5 (4-7)	8 (5-8)*	7 (4-9)	6 (5-8)	8 (6-8)	7 (4-8)	8 (6-9)†	7 (5-9)	8 (5-10)	8 (5-9)†	8 (8-9)	6 (6-9)
Self-efficacy (md)	5 (3-7)	5 (3-8)	4 (3-8)	4 (2-6)	6 (5-8)*	5 (3-6)	3 (3-5)	5 (4-6)	5 (4-7)	6 (5-8)‡	5 (3-6)	5 (3-7)
Social support (md)	6 (2-8)	7 (2-9)	4 (1-8)	6 (3-8)	7 (4-8)	5 (3-8)	5 (3-8)	7 (3-9)	4 (3-6)	5 (3-9)	3 (4-4)	6 (4-8)
Overall statement (md)	7 (4-9)	7 (5-10)	8 (5-9)	5 (4-8)	7 (5-8)	6 (5-8)	5 (3-6)	7 (5-8)*	5 (4-6)	7 (5-9)	7 (5-9)	8 (7-9)

*Significant difference within group between baseline and 1st follow-up; †Significant difference compared with N group at baseline, ‡Significant difference compared with T+N group at baseline. $p<0.05$.

Improvers/non-improvers vs compliers/non compliers

Improvers in the variables leg press, dips, pull-down, step test and TUG had significantly higher compliance compared with non-improvers in the T and T+N groups.

Improvers in the variables of tandem stance and instrumental ADL were significantly older than non-improvers.

There were more men in the T group, and the T group significantly increased their muscle strength. We therefore conducted a separate sex analysis, but observed no differences between improvers and non-improvers.

There were no significant differences between improvers and non-improvers regarding number of continuous medications, BMI, energy intake/kg, or the different statements in the Health Belief Model in the T and T+N groups.

There were no significant differences between compliers and non-compliers regarding age, sex, number of continuous medications, educational level, BMI, FFM, or energy intake/kg at baseline in the T and T+N groups. Nor were there any differences between compliers and non-compliers regarding the different statements in the Health Belief Model at baseline and no changes in estimated ratings between baseline and 1st follow-up in the T and T+N groups.

We also conducted a separate analysis to see whether a limit of 80% compliance altered the results, but this was not the case.

Subjects who improved their energy intake/kg in the N and T+N groups were significantly older than those who did not. There were no other significant differences concerning number of continuous medications, educational level, IAM, physical activity level or compliance regarding nutritional measures.

DISCUSSION

The results of this study indicate the positive effect of a physical training program on muscle strength in community-dwelling, frail elderly people. However, the observed effects were not augmented by the combination with nutritional treatment. These findings are in line with several previous studies (4-7).

Progressive muscle-strength training, especially when performed with stationary equipment, was particularly effective in the lower extremities. This finding was also expected, since this section was the most individualized part of the training program and the lower extremities were more exposed to training through the functional strength training section. Significant differences in lower extremity strength were not observed in comparison with the C group, but the N group. However, both C and N groups received the same physical training advice and, as has been shown in this study, a combination of treatment did not add any extra benefit.

The significant increase did not remain at 2nd follow-up, indicating the need for continuous physical training for this group of frail elderly people. This confirms the well-known fact that muscle strength decreases with physical inactivity.

The small improvements within groups concerning dips and pull-down are probably too small to be clinically relevant. A recent reliability study has shown that there is a variability of -4/+7 kg in the pull-down device, which cannot be explained as an effect of strength training, but rather by fluctuating daily condition and/or motivation (16).

Within-group analyses showed that the T group significantly improved in 7 out of 12 physical performance variables and the T+N group in 3 out of 12. This could be interpreted as if the nutrition intervention program negatively affected the results; however, since there were i) no significant differences between the two groups in the different variables between baseline and 1st follow-up, and ii) a rather small sample size, we do not find this interpretation valid.

From a clinical practice point of view, it is important to discuss the levels of improvement in some of the variables. To our knowledge, there is no scientific evidence available regarding what level of improvement in various aspects of physical performance may be of clinical relevance, and there is an obviously strong call for clinical research in this field. Podsiadlo et al. (24) attempted to find cut-off scores concerning TUG, but they are often difficult to address when evaluating a potential effect. The lack of such studies may be explained by many potential confounding factors and difficulties in setting "relevance limits"; such limits may also differ from person to person. In clinical settings, and where there is a lack of scientific foundation, these judgments probably have to be set individually in relation to a particular elderly person's whole life situation. Ferrucci et al. (35) discussed the influence of factors such as social environment, economic status, cognition and depression, all of which may strongly affect disability over time.

The amount of physical training per week that is required to be beneficial for elderly people is not known. In this study, subjects were regarded as compliers if they had >65% compliance, i.e., they participated on average 1.2 times per week. Previous studies have concluded that physical training less than twice a week is not enough to yield improvements. However, training twice a week may prove difficult for a frail elderly population, especially on a long-term basis (36).

We observed a significant difference between compliers and non-compliers regarding improvement of aspects such as muscle strength. These findings are not surprising, since both specificity and a certain minimum amount of training are most probably necessary to achieve improvements.

In the analysis of compliers/non-compliers, the other included variables showed no significant differences, regardless of a compliance limit of >65% or >80%. There may certainly be other factors involved, such as types and combinations of diseases and injuries etc.

The statements created from the dimensions in the Health Belief Model are probably too superficial to be able to predict compliance or outcome. Other important dimensions to explore could be, for example, vulnerability, locus of control and expectation outcomes.

One of the challenges when designing the present physical training program was to standardize the various sections, both in order to describe training doses and to allow readers to understand how the program was executed in detail so as to be able to reproduce the study. This is rarely the case in many published studies, a fact which has been discussed in a recent review (37).

Subjects were asked to score their effort after each section and they usually scored 3 or 5 on the CR-10 scale, meaning "somewhat tiring" or "tiring". However, some of the subjects scored 3, even though they had to sit down and rest during the aerobic section. Perhaps these types of scales are difficult to understand and interpret for frail elderly people. There may also be a difference in attitudes towards the feeling of effort, which may very well be gender-related.

The heart rate may also have been affected by, for example, treatment with beta-blockers or problems like cardiac arrhythmias. The method for predicting maximal heart rate (220 minus age) has disadvantages, due to the large variations in the applied prediction formula at individual level, but at least gives an indication of the intensity and different levels of the three sections.

Tai chi has been shown to decrease the risk of falls and also to preserve the effect of a strength and balance training program for elderly people (38, 39). When contacting various organizations in Sweden to find instructor classes for Tai chi, it became clear that Tai chi is considered to be more difficult to perform than Qigong, especially for elderly people. The movements of Qigong are less complex and challenging to perform, but both Qigong and Tai chi include training in different standing positions (support areas). Also, Qigong is more widespread in Sweden, especially for the elderly. We chose Qigong instead of Tai chi for these reasons.

We found that the T group exhibited significant, but clinically limited, improvement in two measures of balance: modified figure eight and step test. Frail elderly people probably need much more individualized and targeted balance training to be able to challenge their limits, which are necessary to improve balance.

To our knowledge, this is the first RCT in community-dwelling frail elderly people, age of 75 and over, that has applied individualized dietary counseling and tried to work with food choices and eating patterns instead of standardized supplements. This approach resembles clinical routine practice and also serves educational and participatory purposes. However, the chosen method for nutritional treatment was difficult to standardize, making it difficult to associate clinical effects at follow-up with actual treatment. This may be one reason for the lack of positive results concerning nutritional measurements.

The C group received both general diet and physical training advice, while the T and N groups only received general diet or general physical training advice, respectively, which may explain the lack of improvement in most of the variables. Besides serving as a control intervention, the reason for including the advice was that it might resemble that given in primary care. The C group had a significantly higher education level, which may have had an impact on compliance with given advice. It has been shown that health literacy is of importance in the understanding of health advice (40).

There is no consensus regarding the definition of frailty, and many different definitions appear in the literature (1-3). The definition of frailty used in the present study was chosen on the basis of the published literature at that time, but also for logistic and economic reasons. A narrower definition would probably have resulted in a more homogeneous group. Conversely, it has been suggested that a broad definition increases generalization (35).

The BMI cut-off score for elderly people has been debated (41). In relation to loss of body function, a cut-off score of 18-20 kg/m^2 has been recommended (41). A previous study analyzing the criteria for frailty suggested a BMI cut-off score of 21.7 kg/m^2 in combination with a low level of physical activity (2). In the present study, a cut-off score of BMI <20 kg/m^2 was set for those without weight loss during the last 12 months to include possible underweight.

There are several limitations to this study. The small sample size and large heterogeneity regarding both physical performance and nutritional measurements may be the most important ones, as well as the fairly high drop-out rate. This heterogeneity and the unknown treatment effect(s) for various outcome variables made it difficult to perform a power calculation. We therefore decided to conduct this pilot RCT to provide both methodological and clinical information as a basis for future studies of frail elderly persons.

Another limitation of the study is that the test leaders were not blinded to randomization for logistical and economic reasons.

Furthermore, although the used outcome measurement instruments are well established in the scientific literature, they may not always capture clinically relevant changes, especially in frail elderly subjects. While dual energy X-ray absorptiometry (DXA) is the gold standard for anthropometric measurements, cost factors made it impossible to use this method for all follow-ups. Thus, simple calliper-based anthropometric measurements were used. The reliability of such skin fold measurements has been criticized for its low reliability. One study showed a difference of approximately 10% between two measurements for lean subjects (42). In our study, FFM significantly decreased between baseline and 2nd follow-up in the T group (Table 2). We consider this small decrease to be irrelevant with regard to both the rather low reliability of skin fold measurements and to potential clinical importance.

It is well known that all subjects included in a treatment trial almost never respond to a particular treatment. In this study, we tried to examine more closely the concept of improvers/non-improvers in relation to compliance and other background factors and to treatment with physical training and/or nutrition. However, the analyzed background factors did not show any consistent pattern in our groups. This may be due to the small sample size and there are certainly several other factors involved in this process.

CONCLUSIONS

This study indicates the positive effect on lower extremity muscle strength at 1st follow-up for the T and T+N groups. The combination of T+N did not improve the results compared with T alone. The positive results did not remain at 2nd follow-up, indicating the need for continuous training for this group of frail elderly people. Balance training most probably needs to be more targeted and individualized to be effective for frail elderly persons.

Further studies are needed with larger sample sizes to investigate the effects of these types of interventions, preferably with more targeted interventions, and to explore the underlying mechanisms for improvers/non improvers and compliers/non compliers before any further conclusions can be drawn.

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