ORIGINAL CONTRIBUTION

Effects of a dietetic treatment in older, undernourished, community-dwelling individuals in primary care: a randomized controlled trial

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Abstract

Purpose Undernutrition is a prevalent problem in older, community-dwelling individuals. Aim of this study was to determine the effects of a dietetic treatment in older, undernourished, community-dwelling individuals.

Methods A parallel randomized controlled trial was performed in 146 non-institutionalized, undernourished individuals aged ≥ 65 years in primary care. Participants were randomly assigned to the intervention (referral to and

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Department of Epidemiology and Biostatistics and the EMGO Institute for Health and Care Research, VU University Medical Center, Amsterdam, The Netherlands treatment by a trained dietitian) or control group (no referral). Body weight, physical performance, handgrip strength, energy intake, protein intake and fat-free mass were assessed at baseline, after 3 months and after 6 months.

Results All randomized participants (n = 146) were included in the intention-to-treat generalized estimating equations analysis (72 in intervention and 74 in control group). No treatment effect was found on the primary outcomes body weight ($\beta = 0.49$ kg, 95 % CI: -0.15-1.12), physical performance ($\beta = 0.15$ points, 95 % CI: -0.33-0.64) and handgrip strength ($\beta = 0.49$ kg, 95 % CI: -0.62-1.60). Furthermore, no treatment effect was found for the secondary outcomes. Predefined subgroup analyses showed a treatment effect on body weight in physically active participants ($\beta = 1.25$ kg, 95 % CI: 0.70-2.11) and not in inactive participants ($\beta = -0.20$ kg, 95 % CI: -1.16-0.75).

Conclusions After 6 months, a dietetic treatment by trained dietitians does not lead to increases in body weight and physical functioning in older, undernourished, community-dwelling individuals.

Keywords Undernutrition · Older individuals · Primary care · Dietetic treatment

Introduction

Although undernutrition is present within all age groups, the most vulnerable persons for undernutrition in developed countries are older individuals. Older age is associated with a decreased food intake [1] and higher prevalence of undernutrition [2], resulting from the higher disease rate and the psychological and social changes that occur with

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aging [3–6]. Undernutrition in older individuals is found to be associated with several adverse clinical outcomes such as reduced functional status [7, 8], poorer quality of life [9], higher risk of institutionalization [10] and increased mortality [11–13].

Undernutrition is most prevalent in institutionalized patients, but studies in older, community-dwelling individuals have also shown significant prevalence rates between 15 and 35 % [3, 14]. As in the Netherlands 95 % of individuals aged 65 years and older live independently in the community [15], the absolute number of older, undernourished individuals is highest in this setting. Therefore, it is important to recognize and treat undernutrition in the primary care setting.

No international standardized definition of undernutrition is available. Moreover, there are no internationally accepted protocols for the treatment of undernutrition in older individuals in primary care as only a limited number of randomized controlled trials (RCTs) have been performed. Most nutritional intervention studies were performed in specific hospital or nursing home populations. Furthermore, most RCTs focused on the effect of oral nutritional supplements (ONS) [16]. Much less attention has been given to increasing energy intake via ordinary foods and beverages through individual support by a dietitian. Increasing energy intake via ordinary foods and beverages has the advantage that it offers greater variety and is tailored to individual needs [17]. Beneficial effects of dietetic treatment were found on nutritional intake and body weight in adult COPD outpatients [18], nutritional intake in adult colorectal cancer patients after radiotherapy [19] and mortality in older, hospital patients [20]. In community-dwelling older individuals, a partially RCT was performed to investigate the effect of a dietetic treatment, showing an effect on cognitive function, depressive symptoms and health care use [21]. RCTs in primary care in older, undernourished, community-dwelling individuals focusing on body weight and functional outcomes are lacking. Therefore, we investigated the 6 months effects of dietetic treatment in older, undernourished, communitydwelling individuals in primary care.

Methods

Study design

The Nutrition in Primary Care Study (NPCS) was designed as a randomized controlled trial performed in the region of Amsterdam in the Netherlands between October 2009 and June 2011. The study was in accordance with the Declaration of Helsinki and was approved by the Ethics Review Board of the VU University Medical Center Amsterdam. Written informed consent was obtained from all participants. The study was registered at the Dutch Trial Register (http://www.trialregister.nl) NTR1808.

Recruitment

In the first phase of recruitment, nutritional status was assessed in a total of 3,591 individuals aged 65 years and older in different primary care locations by trained nurses, researchers and research assistants. Individuals were eligible for NPCS if they were non-institutionalized and were identified as undernourished according to the Short Nutritional Assessment Questionnaire 65+ (SNAQ⁶⁵⁺). The SNAO⁶⁵⁺ was recently developed and validated to determine undernutrition fast and feasible specifically in community-dwelling older individuals [22]. Other screening instruments including the assessment of body weight, which is an impractical measure for the home situation, are less specific for assessing undernutrition. Undernutrition was defined as a mid-upper arm circumference (MUAC) <25 cm and/or self report of >4 kg unintentional weight loss within the past 6 months. MUAC was measured with a measuring tape at the center point of the left upper arm to the nearest mm with the arm hanging loosely. Unintentional weight loss was assessed by the question: "Have you unintentionally lost 4 kg or more within the past 6 months?" Individuals were excluded from enrollment if they were under current dietetic treatment, were medically diagnosed with dementia, were not living in vicinity of Amsterdam (where the treatment is provided) or were not speaking the Dutch language. Severely overweight (MUAC > 32 cm) individuals were also excluded from the study as it is unclear whether weight gain would be advisable for these individuals [23]. A MUAC > 32 cm corresponds with a BMI > 28 kg/m², based on data from 2,141 individuals aged ≥ 65 years (data available by request from authors).

In the second phase, all potentially eligible participants received an information letter, accompanied by the informed consent form, and were asked by telephone if they were willing to participate. Those willing to participate were scheduled for the baseline examination, during which cognitive functioning was measured with the Mini-Mental State Examination (MMSE) [24]. Participants with a MMSE score <18 [25] and participants who were unable to stand on the weighing scale were excluded.

Randomization

The randomization was performed by the primary investigator within 1 day after completion of the baseline examination. Random allocation to either the intervention group or the control group was individually performed in blocks of 4 and 6 by using the website randomization.com (http://www.randomization.com). Participants recruited at an outpatient clinic department were randomized with a separate scheme, because they were expected to be more severely undernourished. Participants, researcher and research assistants were no longer blinded for the intervention assignment from this point.

Study protocol

Participants of the intervention group received dietetic treatment from a qualified trained dietitian. The control group received usual care and was not referred to a dietitian through the study. They received a standard brochure of the Netherlands Nutrition Centre with general information about healthy eating habits. To avoid bias of potential prescription of vitamin D as part of the dietetic treatment, all participants were prescribed a combined calcium (1,000 mg calcium carbonate) plus vitamin D (800 IU cholecalciferol) supplement by their general practitioner if this was not already used.

Dietetic treatment

The 18 participating dietitians received a specific training about the treatment of older, undernourished individuals. As there are no internationally accepted protocols for treating undernourished older individuals in primary care, this training was based on a recently developed method for diabetic patients: the PRo-active Interdisciplinary Self-MAnagement (PRISMA) program, which has been shown to have a significant effect on nutritional intake in diabetic patients [26]. PRISMA triggers individuals to consider their own personal risk factors that have led to undernutrition and to choose a specific goal of behavioral change to achieve, using a motivational interviewing technique. The treatment was a combination of both face-to-face and telephone consultations, and the amount of consultations was depending on the nutritional situation, needs and desires of the participant. According to the PRISMA method, a workbook including a questionnaire and a personal action plan on how to successfully achieve the set treatment goals was used. The questionnaire included predefined risk factors associated with undernutrition, for example, weight loss, reasons of eating less, help with shopping and cooking, fatigue, pain and depression. General practical information related to undernutrition was also added to the workbook, for example, information about appetite problems or meal suggestions and recommendations concerning fatigue, nausea and change in taste. The instructed aim of the treatment was to obtain adequate protein and energy intake, preferable by regular foods and beverages. The dietitians were instructed to prescribe additional nutritional supplements and/or tube feeding if the intake of regular foods and beverages was insufficient (<100 % from requirement as calculated by the Harris and Benedict formula +30 % and \geq 1.20 g protein per kg body weight [27–29]). After 6 month follow-up, the dietitians sent an evaluation form to the primary investigator about the number and total duration of the provided consultations and the treatment goals that were set for each participant.

Within 2 days after randomization, the primary investigator contacted a trained dietitian through email and sent an information letter to the participants' general practitioner containing a request for signing and sending a referral letter to the dietitian. The dietitians were instructed to schedule the first consult within 5 days and to send the above-mentioned workbook to the participants' home to be filled in before the first consult. The personal action plan was completed during the first consultation and discussed during each consecutive consultation. The dietetic treatment was covered by the basic health insurance of the participants.

Measures

Two follow-up examinations were performed 3 and 6 months after the baseline examination. All examinations took place at the participants' home and were executed by a trained researcher or research assistant using a standardized protocol. Socio-demographic factors, body height, presence of chronic diseases and medication use were assessed at the baseline examination. Other measures were assessed at all examinations.

Primary outcome measures

Body weight was measured without shoes to the nearest 0.5 kg using a calibrated mechanical scale (Seca 761). Adjustments were made for clothing (-1.77 kg for men; -1.13 kg for women), and in deviating situations, adjustments were made for shoes (-0.40 kg for men; -0.28 kg for women) or corset (-1 kg) (respectively, 3 and 1 % of all assessments) [30, 31].

Physical performance was assessed using the Short Physical Performance Battery which consists of a 4-m walk test, repeated chair stands test and standing balance test [32]. The total score ranged from 0 (worst performance) to 12.

Handgrip strength (kg) was measured twice on each hand using a handheld dynamometer (JAMAR; Sammons Preston, UK). The mean value of the maxima of both hands was used. If the left or right handgrip strength measure was missing at an examination, this measure was also set to missing at the previous or follow-up examinations.

Secondary outcome measures

A food diary was filled in by the participant the day prior to each examination and was reviewed for completeness by the researcher (or assistant) during the examination. If missing, a 24-hour recall was conducted during the examination. Daily energy (kcal) and protein (gram) intake were calculated using the NEVO Dutch Food Composition Table 2006 [33]. A copy of the baseline examination food diary and the calculation of the baseline energy and protein intake were send to the treating dietitian.

Whole-body resistance (R, Ohm) was measured at the left side of the body at a frequency of 50 kHz using a Bodystat 1500 MDD (Euromedix, Belgium). Fat-free mass (kg) was predicted with the formula of Kyle (2001) [34]. Participants with an invalid measurement (fat percentage <5 %) were excluded from the analysis (7.5 %) [35]. Other reasons for missing data were as follows: shoes could not be taken off (1.3 %), dysfunction of the equipment (2.0 %), pacemaker (3.0 %), presence of stocking or bandages (3.8 %) and not able/refuse (5.3 %).

Statistical analysis

Linear generalized estimating equations (GEE) analysis with an exchangeable correlation structure was used to analyze the effectiveness of the intervention. This longitudinal analysis technique is suitable to compare the course over time of the repeated outcome measures between two groups. A minimum of 62 participants per group was required to detect a statistically significant (P < 0.05) treatment effect of 2.23 % [36] in body weight after 6 months with 80 % power. The GEE analyses included all randomized participants and were performed according to the intention-to-treat principle with the last-observationcarried-forward. The outcome measures were analyzed as dependent variables using intervention group as the independent variable. All analyses were adjusted for the baseline values of the outcome variable which led to equal starting points for both groups. Results are presented as beta coefficients with 95 % confidence intervals and can be interpreted as the mean difference between the intervention and the control group. A two-tailed significance level of $\alpha = 0.05$ was used.

To study whether the effect of the intervention differed between the first 3 months and the next 3 months, the variables time and intervention*time were added to the model. Furthermore, predefined subgroup analyses were performed for the primary outcome measures according to sex, assessment criteria of the SNAQ⁶⁵⁺ (MUAC < 25 cm, unintentional weight loss \geq 4 kg or both criteria) and physical activity measured with the validated LASA Physical Activity Questionnaire [37] (stratified at the median of 728 min/week). In addition, post hoc analyses were performed for the primary outcome measures according to appetite (poor/normal appetite) and energy intake (stratified at the median of 1,568 kcal/day).

All statistical analyses were performed using SPSS version 16.0 (SPSS, Chicago, USA).

Results

The participant flow of the NPCS is shown in Fig. 1. During the first recruitment phase, nutritional status was assessed with the SNAQ⁶⁵⁺ in 3,591 individuals. A total of 731 individuals (20 %) were undernourished, of which 362 refused to participate and 211 were not eligible for enrollment. During the second recruitment phase, 158 of the 520 eligible individuals (30 %) were enrolled for the baseline examination of which 12 were excluded before randomization. In total, 72 participants were allocated to the intervention and 74 to the control group. The majority of the participants were recruited in general practices (n = 62), followed by a home care organization (n = 45), an outpatient clinic department (n = 22), senior citizen centers (n = 13), advertisements (n = 3) and pharmacies (n = 1). The recruitment locations did not differ between the intervention and control group (P = 0.90). A total of 127 participants completed the 6 months examination: 62 (86 %) in the intervention group and 65 (88 %) in the control group. The reasons for dropout are described in Fig. 1. There were no statistically significant differences in baseline characteristics between participants who discontinued early and study completers, except for education level. A low education level was present in 56 % of those who discontinued and in 18 % of the study completers (P = 0.002).

The baseline characteristics of the intervention and control group are shown in Table 1. Mean age of the total study population was 80.5 year (SD 7.5), and 64.4 % was women. One out of five participants suffered from three or more chronic diseases, and two out of five participants used five or more medications. Thirty to forty percent reported a poor appetite and depressive symptoms. After 3 months, 53 % of the intervention group and 65 % of the control group were using calcium plus vitamin D supplements (P = 0.20) and 25 % of the intervention group and 10 % of the control group were using ONS (P = 0.02). After 6 months, 63 % of the intervention group and 66 % of the control group were using calcium plus vitamin D supplements (P = 0.58) and 37 % of the intervention group and 12 % of the control group were using ONS (P = 0.001). Main goals of the treatment during the first consult, as indicated by the dietitian in the evaluation form, were preventing further weight loss (35 %) and gaining body

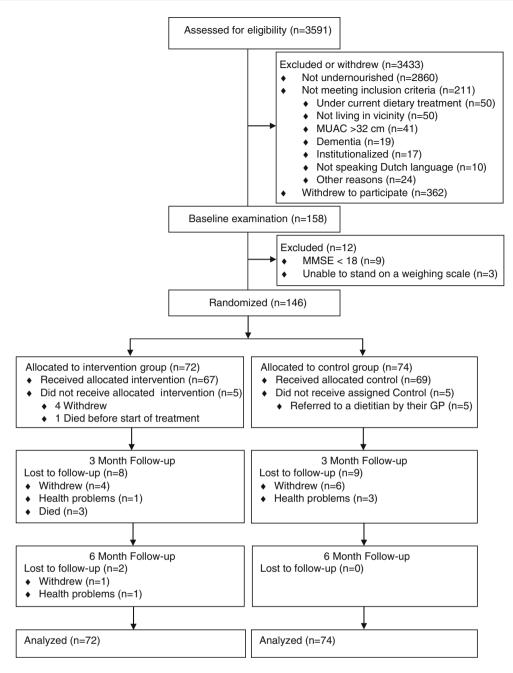


Fig. 1 Consort flow chart Nutrition in Primary Care Study. *MMSE* Mini-Mental State Examination; *MUAC* mid-upper arm circumference; $SNAQ^{65+}$ Short Nutritional Assessment Questionnaire 65+

weight (27 %). Participants in the intervention group received on average 2.4 (SD 1.4) hours dietetic consultations and the control group 0.2 (SD 0.9) hours (P < 0.001).

The mean values of the primary outcome measures at the 3 examinations and the results of the GEE analyses are shown in Table 2. No treatment effect on any of the primary outcome measures was observed. The treatment effect during 6 months follow-up was 0.49 kg on body weight, 0.15 points on physical performance and 0.49 kg on handgrip strength. The results of the GEE analyses for the secondary outcomes are shown in Table 3. No treatment effect was found on the secondary outcomes.

Predefined subgroup analyses showed that the treatment effect was not modified by time, sex or the assessment criteria of the SNAQ⁶⁵⁺ (P > 0.10), but was modified by physical activity (statistically significant interaction with body weight (P = 0.03), but not with physical performance and handgrip strength). The treatment effect was 1.25 kg on body weight in physically active participants (Table 4), and this means that physically active participants who were

Table 1 Baseline characteristics of the participants	Characteristics	Intervention $(n = 72)$	Control $(n = 74)$
	Age (year)	80.6 ± 7.5	80.5 ± 7.5
	Women, n (%)	45 (62.5)	49 (66.2)
	Education, $n (\%)^{a}$		
	Low	13 (18.8)	19 (26.0)
	Medium	43 (62.3)	43 (58.9)
	High	13 (18.8)	11 (15.1)
	Income, $n (\%)^{b}$		
	Low	5 (6.9)	9 (12.2)
	Medium	24 (33.3)	17 (23.0)
	High	33 (45.8)	38 (51.4)
	Unknown/refuse	10 (13.9)	10 (13.5)
	Living alone, n (%)	43 (60.6)	53 (71.6)
	Help with personal care, n (%)		
	No help	50 (70.4)	53 (71.6)
	Informal help	2 (2.8)	2 (2.7)
Values are meen (SD) unless	Professional help	19 (26.8)	19 (25.7)
Values are mean (SD) unless otherwise stated	Help with household care, n (%)		
MMSE Mini-Mental State	No help	21 (30.0)	21 (28.4)
Examination; MUAC mid-upper	Informal help	12 (17.1)	19 (25.7)
arm circumference; $SNAQ^{65+}$	Professional help	37 (52.9)	34 (45.9)
Short Nutritional Assessment Questionnaire 65+	$SNAQ^{65+}$ criteria undernutrition, n (%)		
^a Categories education level: "low" = no education completed and lower general	Weight loss ≥ 4 kg/6 months	23 (31.9)	26 (35.1)
	MUAC < 25 cm	35 (48.6)	37 (50.0)
	Both criteria	14 (19.4)	11 (14.9)
education; "medium" = lower	BMI (kg/m ²)	21.6 ± 3.1	21.7 ± 3.6
vocational education, intermediate general education, intermediate vocational education and higher general education; "high" = higher vocational education and scientific education ^b Categories household monthly income: "low" $\leq $ €900; "medium" €901–€1299; "high" $\geq $ €1300 ^c Assessed by the Center for Epidemiologic Studies	MUAC (cm)	24.8 ± 3.3	24.7 ± 2.6
	Number of chronic diseases, n (%)		
	0	14 (19.4)	19 (25.7)
	1	33 (45.8)	19 (25.7)
	2	11 (15.3)	20 (27.0)
	≥3	14 (19.4)	16 (21.6)
	Number of used medication, n (%)		
	0	5 (6.9)	9 (12.2)
	1–2	14 (19.4)	18 (24.3)
	3-4	24 (33.3)	15 (20.3)
Depression scale (CES-D, range	≥5	29 (40.3)	32 (43.2)
$0-60$). Scores ≥ 16 were	Use of calcium plus vitamin D supplement, n (%)	15 (21.1)	13 (17.8)
defined as depressive symptoms ^d Assessed by the question:	Use of oral nutritional supplements in past month, n (%)	11 (15.5)	8 (10.8)
"How is your health in	Poor appetite past week, n (%)	24 (34.3)	29 (39.2)
general?", with response	MMSE score (range 18–30)	27.0 ± 2.6	26.6 ± 3.1
categories "sometimes good, sometimes poor" and "poor" defined as poor self-rated health	Depressive symptoms, $n (\%)^{c}$	25 (36.2)	26 (35.1)
	Poor self-rated health, $n (\%)^{d}$	9 (12.7)	6 (8.1)

treated by a dietitian gained on average 1.25 kg more body weight compared to physically active participants who were not treated by a dietitian. No statistically significant effect on body weight (-0.20 kg, P = 0.67) was found in physically inactive participants. Post hoc analyses showed that for appetite, a statistically significant interaction was found with body weight (P = 0.003) and for energy intake with physical performance (P = 0.10) and handgrip strength (P = 0.02). The treatment effect was 1.21 kg on body weight in participants with a normal appetite versus

Table 2Primary outcomemeasures at all examinationsand mean difference during6months follow-up

^a The β coefficient (and *P* value) represents the overall treatment effect on the outcome measures over time (adjusted for baseline) and was derived from a generalized estimating equation (GEE) model (coefficient on study group)

Table 3 Secondary outcomemeasures at all examinationsand mean difference during 6months follow-up

^a The β coefficient (and P value) represents the overall treatment effect on the outcome measures over time (adjusted for baseline) and was derived from a generalized estimating equation (GEE) model (coefficient on study group)

Outcome measure	es Baseline	3 months	6 months	Beta (95 % CI) ^a	P Value
Body weight (kg)					
Intervention	58.0 (11.2)) 58.2 (11.4)	58.3 (10.9)	0.49 (-0.15-1.12)	0.13
Control	57.5 (9.9)	57.4 (9.9)	57.0 (9.7)		
Physical perform	ance score				
Intervention	7.4 (3.2)	7.5 (3.1)	7.2 (3.3)	0.15 (-0.33-0.64)	0.53
Control	7.2 (3.4)	7.1 (3.2)	7.1 (3.6)		
Handgrip strengti	h(kg)				
Intervention	21.1 (9.6)	21.1 (8.9)	21.6 (9.1)	0.49 (-0.62-1.60)	0.39
Control	21.3 (8.5)	21.2 (8.9)	21.4 (8.7)		
Outcome	Pasalina	3 months	6 months	Pote $(05 \% \text{ CD})^a$	D Volu
Outcome variables	Baseline	3 months	6 months	Beta (95 % CI) ^a	P Value
variables		3 months	6 months	Beta (95 % CI) ^a	P Value
variables		3 months 41.9 (9.2)	6 months 41.9 (9.2)	Beta (95 % CI) ^a	P Value
variables Fat-free mass (kg	·)			· · · ·	
variables Fat-free mass (kg Intervention Control	40.9 (8.7) 39.9 (7.6)	41.9 (9.2)	41.9 (9.2)	· · · ·	
variables Fat-free mass (kg Intervention Control Energy intake (kc	40.9 (8.7) 39.9 (7.6)	41.9 (9.2)	41.9 (9.2)	· · · ·	
Variables Fat-free mass (kg Intervention Control Energy intake (kc Intervention	40.9 (8.7) 39.9 (7.6)	41.9 (9.2) 40.4 (7.6)	41.9 (9.2) 40.4 (7.6)	-0.02 (-0.93-0.79)	0.95
variables Fat-free mass (kg Intervention Control Energy intake (kc Intervention Control	40.9 (8.7) 39.9 (7.6) al) 1,655.3 (691.9) 1,726.5 (536.0)	41.9 (9.2) 40.4 (7.6) 1,697.6 (594.0)	41.9 (9.2) 40.4 (7.6) 1,770.9 (714.9)	-0.02 (-0.93-0.79)	0.95
Variables Fat-free mass (kg Intervention Control Energy intake (kc Intervention	40.9 (8.7) 39.9 (7.6) al) 1,655.3 (691.9) 1,726.5 (536.0)	41.9 (9.2) 40.4 (7.6) 1,697.6 (594.0)	41.9 (9.2) 40.4 (7.6) 1,770.9 (714.9)	-0.02 (-0.93-0.79)	0.95

-0.79 kg in participants with a poor appetite. The treatment effect was 1.69 kg on handgrip strength in participants with a low energy intake versus -0.92 kg in participants with a high energy intake. Additional subgroup analyses were performed for cognitive functioning, depressive symptoms and professional help with personal care. The treatment effect was 1.02 kg (95 % CI -0.04-2.08, P = 0.06) on body weight in participants with a low MMSE score (≤26) and 0.17 kg (95 % CI -0.60-0.93, P = 0.67) on body weight in participants with a higher MMSE score (>26). The treatment effect was -0.62 kg (95 % CI - 1.70 - 0.46, P = 0.26) on body weight in participants with depressive symptoms (CES-D > 16) and 1.04 kg (95 % CI 0.27–6.68, P = 0.01) on body weight in participants with no depressive symptoms (CES-D < 16). Finally, the treatment effect was 1.11 kg (95 % CI 0.03–2.20, P = 0.05) on body weight in participants with professional help with personal care and 0.26 kg (95 % CI -0.52-1.03, P = 0.52) on body weight in participants without professional help with personal care.

Discussion

This study was designed to determine the effects of a dietetic treatment in older, undernourished, community-

dwelling individuals. The treatment was provided by regular dietitians working in primary care who received an additional training on treating older, undernourished individuals. After 6 months, no treatment effect was observed on the primary outcomes body weight, physical performance and handgrip strength, and on the secondary outcomes fat-free mass, energy intake and protein intake.

To our knowledge, this is the first randomized controlled trial examining the effect of dietetic treatment alone on body weight and functional outcomes in older, undernourished, community-dwelling individuals. Previous studies in primary care focused on the effect of a standard prescription of ONS [16]. The effect of dietetic treatment alone in older, undernourished individuals was only investigated in a study including hospitalized patients [20]. In that study, an individualized dietetic treatment consisting of 4 consults, whereby ONS was prescribed if needed, was compared to standard hospital care. A positive treatment effect was shown on the Mini Nutritional Assessment score and on mortality after 6 months follow-up, but not on body weight or nutritional intake. The latter results are in line with our results in a primary care setting.

There are several characteristics of the treatment design, treatment implementation and the participants themselves that could have contributed to the absence of a treatment effect in our study. A component of the treatment design

Subgroups Body weight Physical performance score Handgrip strength Beta (95 % CI) P Value Beta (95 % CI) P Value Beta (95 % CI) P Value Physical activity <728 min/week -0.20(-1.16-0.75)0.67 0.27(-0.50-1.03)0.49 -0.32(-2.01-1.38)0.72 ≥728 min/week 1.25 (0.70-2.11) < 0.001 0.29 (-0.29 - 0.88)0.32 1.30(-0.14-2.74)0.08 Appetite last week Poor appetite -0.79(-1.86-0.27)0.14 0.22(-0.80-1.25)0.67 1.43 (-0.60 - 3.45)0.17 Normal appetite 1.21 (0.45-1.96) 0.002 0.20 (-0.34-0.74) 0.47 0.09(-1.26-1.43)0.90 Energy intake <1,568 kcal/day 0.59(-0.38-1.55)0.23 0.60(-0.10-1.30)0.09 1.69(0.10 - 3.28)0.04 \geq 1,568 kcal/day 0.57 (-0.36-1.49) 0.23 -0.20(-0.86-0.46)0.55 -0.92(-2.37-0.52)0.21

Table 4 Predefined and post hoc subgroup analyses for physical activity, appetite and energy intake at baseline

that may have played a role was the duration of follow-up. Previous studies using ONS showed statistically significant positive effects on body weight after 6 months follow-up [38, 39], demonstrating that treatment effects of a nutritional intervention are detectable after this follow-up duration. However, in our study, treatment was completed in 78 % of the intervention group, and 22 % was still in treatment at 6 months based on the information from the dietitians' evaluation form. We cannot exclude that the effects of a dietetic intervention are established later than the effects of ONS, and more long-term studies are needed. With respect to the treatment implementation, all participating dietitians received an extensive training about the preferred treatment. A regular primary care dietetic treatment, complemented with additional training, is probably not sufficient to achieve effects in this population when focused on nutrition only. The study population was also quite frail: mean age was high, most participants were chronically undernourished based on a low MUAC, and the majority was suffering from one or more chronic diseases and was using multiple medications. Dietetic treatment only may not have been sufficient to improve nutritional status in frail older persons. Specific characteristics of the participants may also have contributed to the lack of a treatment effect, as not all participants in the intervention group were motivated to follow a treatment or were willing to change their diet. At baseline, most participants (86 %) were aware of the importance of a good nutritional status, but only 36 % reported to be willing to receive a specific treatment for undernutrition and 24 % reported to be willing to change their diet if needed. Finally, similar to all other studies focusing on the treatment of undernutrition, we cannot ensure that the participants were truly undernourished, as still no golden standard exists. More future studies are required to determine who will benefit from what specific dietetic intervention in order to effectively treat undernutrition in older, community-dwelling individuals. In addition, the effects of a multidisciplinary approach of the often complex situation that may have caused undernutrition should be investigated.

Subgroup analyses showed a statistically significant treatment effect on body weight in individuals with a normal appetite and in those who were physically active at baseline. This probably implies that for individuals with a poor appetite and for those with a low physical activity level, other intervention strategies might be preferred. For example, for those with a low physical activity level, a combination strategy might be considered as the combination of resistance exercise and nutrition may play an important role in improving muscle mass, muscle strength and functionality [40]. For those with a poor appetite, interventions might be more focusing on strategies for increasing appetite. Only for relatively "healthy" individuals, the investigated dietetic treatment might be effective. This thought was substantiated by the results of additional subgroup analyses, showing a statistically significant treatment effect on body weight in individuals with no depressive symptoms and in those with professional help with personal care. However, the treatment effect was not found on functional outcome measures in the subgroup analyses. Therefore, the results of the performed subgroup analyses should be interpreted carefully, and beneficial effects on functional outcome measures should first be established in future studies before implementing this strategy.

A major strength of this study is the drop out rate of 13 %, which is relatively low compared to other 6 months nutritional intervention studies in older individuals [20, 39, 41], especially when considering the high frailty level of the study sample. Another important strength was the study setting, as the study was conducted using trained dietitians working in a regular primary care setting. This makes the results applicable to the usual care situation.

From the current study, we can conclude that dietetic treatment of older, undernourished, community-dwelling

individuals as currently provided by trained dietitians in primary care in the Netherlands had no effect on body weight, physical performance, handgrip strength, fat-free mass, energy intake and protein intake after 6 months. A long-term, multidisciplinary approach for successful treatment of undernutrition in primary care should be investigated in future studies.

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Conflict of interest The authors declare that they have no conflict of interest.

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