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The effect of protein-enriched products on protein intake and functional status of older adults after hospital discharge: *The Cater with Care effect study*

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Preface

This thesis was written as a part of the two-year master's programme Nutrition and Health at Wageningen University. From January 2015 until June 2015 I studied the effect of protein-enriched Cater with Care products on the protein intake and functional status of older adults. This was done as part of the Cater with Care effect study, performed in a collaboration between Hospital Gelderse Vallei, Ede and Wageningen University.

The choice for conducting my thesis within the Cater with Care project was mostly driven by my background in Nutrition and Dietetics. Having worked as a dietitian in elderly care has taught me much about the challenges in improving the dietary intake of older, and often vulnerable, individuals.
I believe that the Cater with Care project is a relevant initiative to optimize nutritional care for elderly patients in the nearby future.

I can say I feel proud of this thesis as the final result of six months of hard work. The process of finishing this thesis was not always easy and there certainly were some ups and downs along the way. Nevertheless, I believe that the knowledge and experience gained during this process forms a solid base for my future career in nutrition research.

I would like to thank my main supervisor Nicole de Roos and my daily supervisor Janne Beelen for their positive guidance, relevant feedback and support. Thank you both for making me feel like a true member of the Cater with Care team.

Furthermore, I would like to thank all other students who were part of the Cater with Care project. Anne, Emilie, Myrte, Rick and Cora: it was fun working together as a team. Thank you for your tips and support. Also, I would like to thank Astrid and Renske, for their calming words, laughter and relevant advice.

Finally, my gratitude goes out to all participants of the Cater with Care effect study. I was truly amazed by their high level of motivation to participate in the study, even though this was not always easy due to health reasons. Furthermore, I appreciate their willingness to share personal information and to undergo several measurements in order to contribute to a successful completion of the Cater with Care effect study.

Merel Snellen
Wageningen, June 2015

Abstract

Introduction: Maintaining muscle mass and function is essential to prevent functional decline and loss of independence. This requires an adequate protein intake. A recently proposed protein recommendation for acute and chronically ill elderly was set at 1,2 - 1,5 g/kg BW/day. However, many elderly admitted to or recently discharged from hospital do not reach this high intake. To help increase their protein intake, Cater with Care (CwC) products were developed: a variety of protein-enriched foods and drinks regularly consumed by elderly.

Objectives: To study the effects of supplementing a standard home-based diet with a variety of protein-enriched CwC products on total daily protein intake and functional status of older adults (≥ 65 years) during 12 weeks after hospital discharge.

Methods: This study was a non-blinded randomized controlled trial with two treatment arms. The intervention group received CwC products in addition to its standard diet. The control group received non-protein-enriched products. Participants had a free choice in type and amount of products, which were delivered at home twice a week. Measurements were performed at week 2, 6 and 12. Dietary intake was assessed using a dietary food record assisted 24-h recall. Functional status was measured using the Barthel Index (BI) and the Short Physical Performance Battery (SPPB).

Results: These preliminary results included data of 43 participants (mean age: 77,2 years). Compared to the controls (N=22), protein intake of the intervention group (N=21) was significantly higher at all three time points. The difference in mean intake was 0,6 g/kg BW/day at week 2 & 6 and 0,4 g/kg BW/day at week 12. Overall, 82% of participants in the intervention group achieved the intake level of 1,2 g/kg BW/day, against 48% of the controls. The BI score of the intervention group remained constant, whereas the score of the controls showed a small (1 point) decrease over time. However, this decrease was not statistically significant at α: 0,017 (P= 0,022). A small (1 point) and non-significant improvement in median SPPB score was seen in both the intervention (P= 0,439) and control group (P= 0,368).

Conclusions: Supplementing a standard diet with a variety of CwC products is an effective approach for older adults to achieve the proposed protein intake level of 1,2 – 1,5 g/kg BW/day. Moreover, starting the use of the CwC products in the hospital and continuing to use them after discharge, might help to maintain rather than improve functional status of older adults, but this finding should be confirmed in the final analysis of the CwC effect study.

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1. Introduction

The number of older adults within our society is rapidly increasing. In the year 2012 the Dutch population consisted of 2,7 million people aged 65 years and above. This number is estimated to increase to 4,7 million people in 2040, accounting for 26% of the total population [1]. In accordance with Dutch government policy the vast majority of this older population will be living independently, for which an optimal health status is an important criterion [1]. However, as people get older they often face multiple chronic diseases and physiological changes that have a negative effect on food intake and thereby increase the risk of undernutrition [2]. Undernutrition is an important problem in the Netherlands, particularly among hospitalized older adults. Depending on the definition used the prevalence is estimated to be 18 or 33% [3]. A poor nutritional status is associated with several adverse clinical outcomes such as an impaired immune function, delayed wound healing and prolonged treatment duration [4]. Moreover, as a result of an inadequate dietary intake combined with reduced physical activity, older adults are prone to develop sarcopenia [5]. Sarcopenia is defined as the age-related loss of skeletal muscle mass and function, which increases the risk of falls, mobility disorders and difficulties in performing activities of daily living (ADL) [4-6]. This decline in functionality subsequently reduces the independence and quality of life of older individuals [7].

An adequate dietary protein intake plays an important role in the prevention and management of undernutrition and sarcopenia. It is believed that muscle mass and function of older adults is better maintained with a protein intake at a higher level than the current recommended dietary allowance (RDA) of 0,8 grams per kilogram body weight per day (g/kg BW/day) [8, 9]. The need for more dietary protein is partly due to an age-related decline in anabolic response to the ingested protein [8, 9]. For this reason, the PROT-AGE study group recently recommended a daily intake as high as 1,2 – 1,5 g/kg BW/day for older individuals suffering from acute or chronic diseases [8]. However, studies show that the intake of hospitalized and recently discharged older adults averages 0,9 g/kg BW/day, which is well below the levels as recommended by the PROT-AGE group *(unpublished data in Master Thesis Joyce van Geel, 2014)* [10, 11].

In general, it is difficult for elderly people to simply increase the amount of food they consume in order to obtain a sufficient protein intake. Many experience a loss of appetite due to physiological changes such as impaired senses of taste and smell and increased satiation signals [2, 12, 13]. This situation is worsened when they are acute or chronically ill and suffer from side effects of medication, poor dentition, functional disabilities or social isolation and depression [2, 12, 13]. Consequently, when an adequate protein intake is not achieved through regular foods, often oral nutritional supplements (ONS) are advised [12, 14]. However, compliance for ONS is generally poor because of a low palatability, negative effects on satiety and gastrointestinal side effects [12, 14, 15].

To overcome elderly's difficulties in consuming enough protein, enriching products they are used to consume within their daily menu might be an effective alternative. For this reason, the Cater with Care consortium developed a variety of protein-enriched regular foods, such as bread, beverages and soups, tailored to the needs and preferences of elderly people [16]. The effectiveness of these products in increasing the dietary protein intake of older adults at risk of undernutrition will be assessed in the Cater with Care effect study.

Recently, a trial by Stelten et al. [10] already found promising short-term results for protein-enriched regular foods in acute hospitalized elderly patients. In this study, supplementing a standard hospital menu with protein-enriched bread and drinking yoghurt, resulted in a mean protein intake of 1,1 g/kg BW/day in the intervention group compared to 0,9 g/kg BW/day in the control group [10]. Despite this improved mean intake, still the majority (64%) of patients in the intervention group failed to meet the recommended intake level of 1,2 g/kg BW/day. Moreover, Stelten and colleagues did not yet examine whether a longer-term use of the products also resulted in a better clinical outcome. Therefore, the recent Cater with Care effect study wants to examine whether continuing to use a variety of protein-enriched regular products after hospital discharge, improves the functional recovery of older individuals.

Physical function of elderly people is commonly measured in terms of mobility, endurance or activities of daily living (ADL) [8]. Preservation of independence in ADL is one of the most important goals of (medical) treatment of older persons [17]. Next to that, it is an important determinant of quality of life [7]. To assess ADL, the Barthel Index (BI) [18] is often used. This is an easy to apply self-report instrument to evaluate a patient's level of independence in 10 items of basic ADL, including: feeding, bathing, mobility and transfers [19]. Until now, only a few studies have been published on the effects of dietary protein supplementation on the BI score of older individuals. Besides, most trials used protein supplementation in the form of ONS. For example, McMurdo and colleagues [20] supplied a liquid formula containing 40 grams of dietary protein to undernourished older adults upon hospital discharge. Unfortunately, after a 16-week study period no significant effect on change in BI score was found. This was also the case for the studies of Wouters-Wesseling et al. [21] and Smoliner et al. [22]. In a more recent trial by Lee et al. [23], the use of a liquid supplement containing 9,5 grams of soy-protein did result in a significant improvement in BI score of geriatric nursing home residents. However, the effect was only seen after 24 weeks and when adjusting for baseline nutritional status using Generalized Estimating Equations (GEE).

The limited effects found within these studies, might be the result of different factors. First of all, three of the studies [21-23] were conducted in nursing home residents, of which some were very old (mean age: 85 years) and suffering from dementia [21]. Since disabilities in ADL may have been one of the causes of nursing home admission, improvement in the BI score of this population seems unlikely. Moreover, in the study of Wouters-Wesseling et al. [21] participants had a median BI score of 5 on a 20-point scale at baseline. Since the sensitivity of the BI is affected by so called "floor and ceiling effects" [24] [25], a (small) change in the ADL-independence of this already severely dependent study population might have gone undetected. Finally, the BI being a self-report measure of physical function, might play a role. Self-report measures reflect people's perception of their ability to (independently) perform a task [26]. These often

called ‘subjective’ measures may be inaccurate when people over- or underestimate their capabilities [27]. In contrast to self-report measures, performance-based measures of physical function examine people’s ability by observing their physical performance [26]. In early studies these measures were found to have a better reproducibility and greater sensitivity to change [28, 29]. Next to that, they were considered to be less influenced by external factors such as poor cognition and education [28, 29]. For this reason, performance-based measures are sometimes described as being a more objective and valid method to assess physical function in elderly people [27]. That this is not always the case was shown in a recent study by Latham et al. [30]: they did not find the psychometric properties of performance-based measures to be better than those of self-report measures. Instead of one type of measure being superior to the other, it is believed that they provide complementary information regarding physical functioning [30]. In fact, a study by Volpato et al. [31] even found that a low score on a performance-based test at hospital discharge and one month after discharge, was predictive for the level of self-reported difficulties in ADL over a one-year follow-up period. For this reason, previous studies concluded that combining both types of measures allows to obtain a more complete overview on functional status [27, 30].

One of the performance-based measures commonly used in elderly people is the Short Physical Performance Battery (SPPB). The SPPB comprises a set of three objective measures of lower extremity function: a balance test, a chair rise test and a gait speed test [29]. Its reliability and responsiveness to change were already demonstrated in a study by Ostir et al. [32]: the SPPB had an excellent test-retest reliability in measurements performed one week apart and a good long-term test-retest reliability in measurements performed 6 months apart. Moreover, recent trials demonstrated that protein supplementation in the form of ONS positively affects the SPPB score of older individuals. For example, Tieland and colleagues [33] found a significant increase in the SPPB score (+ 1 point) of frail elderly subjects supplied with a liquid formula containing 30 grams of protein during a 24-week study period. Also, Kim and colleagues [34] found that, compared to the decline in the control group, the SPPB score remained stable in frail older adults receiving a liquid formula containing 25 grams of protein during a 12-week study period. At this point, the effect of protein-enriched regular products on the SPPB score of elderly people, has not yet been examined.

Given these considerations, both the BI and the SPPB will be used within this thesis to assess whether supplementing a standard home-based diet with a variety of protein-enriched regular products (Cater with Care) improves the functional recovery of older individuals (≥ 65 years). At first, it will be examined whether the use of the Cater with Care products increases dietary protein intake to the recommended level of 1,2 – 1,5 g/kg BW/day. The aim is to find a between-group difference of at least 0,3 g/kg BW/day at 12 weeks after hospital discharge. Subsequently, it will be examined whether a higher protein intake results in a better functional status (either a greater change in BI score or SPPB score) in this three-month post-discharge period.

2. Materials and methods

2.1 Study design

This thesis was part of the Cater with Care (CwC) effect study which started in hospital Gelderse Vallei, Ede, the Netherlands, in October 2014 and was still being carried out at the time this manuscript was written. The study was designed as a randomized controlled trial, consisting of two treatment arms. The intervention group received a variety of protein-enriched CwC products in addition to its standard diet. The control group received non-protein-enriched variants of some of the CwC products. The effect study consisted of two phases: a hospital and a home phase. The hospital phase started within 2 days after admission and lasted until the day of discharge. Patients received the products as part of the hospital menu. Data were collected within the first four days after admission and on the day before discharge. The home phase started directly after patients left the hospital. During this phase products were delivered at home twice a week to participants in the intervention as well as the control group, but only for the first 12 weeks. Data were collected by trained students who visited the participants at home at 2, 6 and 12 weeks after hospital discharge. In addition, a final measurement was conducted after a follow-up phase of another 12 weeks without the investigational products (week 24). For this thesis, only the data that were collected during the first 12 weeks after hospital discharge were used. Between-group comparisons were made with the data collected at week 2, 6 and 12. Figure 1 gives a complete overview of the study design.

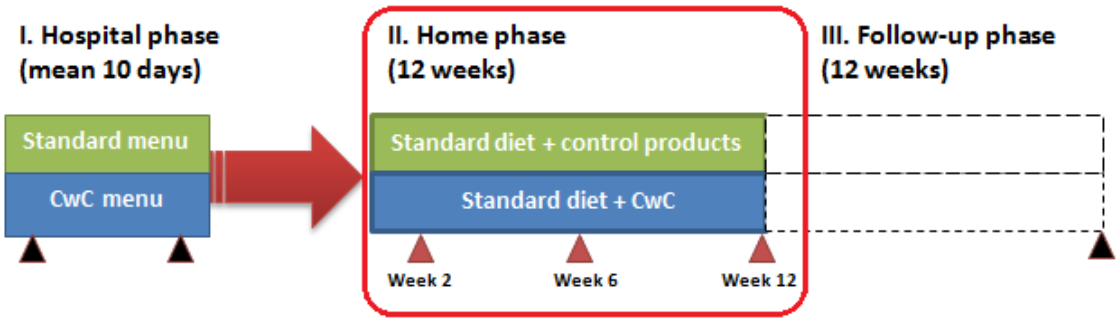

Figure 1: Schematic overview of the study (triangles represent measurement moments, red frame marks the focus of this thesis).

2.2 Participants

All elderly patients (≥ 65 years) admitted to the wards of Pulmonary medicine and Geriatric medicine of hospital Gelderse Vallei were screened for eligibility. Those eligible on the basis of the criteria as listed in section 2.2.1 received additional written information about the study and were asked for their consent to participate in the hospital phase. Subsequently, participants of the hospital phase were further checked for eligibility for the home phase. These patients were visited by a research assistant as soon as the day of discharge was known and received additional written information and an informed consent form for the home phase. The study was approved by the Medical Ethics Research Committee of the Wageningen University.

2.2.1 Inclusion and exclusion criteria

Patients had to meet all of the following inclusion criteria for the hospital phase:

- admitted to the wards of Geriatric medicine or Pulmonary medicine in hospital Gelderse Vallei;
- aged 65 years or over;
- eligible to receive a standard protein enriched menu based on hospital protocol;

Exclusion criteria for the hospital phase were:

- unwilling to give consent for gathering data from the medical record or meal service system;
- unable to understand the Dutch language
- suffering from food allergies, food intolerances or other dietary restrictions that prevented the patient from receiving the standard protein enriched menu or Cater with Care products based on the judgement of a dietitian and/or medical staff;
- expected length of hospital stay < 2 days;
- suffering from renal insufficiency (eGFR < 30ml/min);
- starting with tube feeding or total parenteral nutrition within 2 days after admission;
- a refeeding syndrome score > 0 based on a screening tool of hospital Gelderse Vallei for refeeding risk;
- suffering from delirium at admission;
- receiving palliative care.

Patients had to meet all of the following inclusion criteria for the home phase:

- included in the hospital phase of the study;
- signed informed consent to continue treatment and study participation after hospital discharge.

Exclusion criteria for the home phase were:

- going to a nursing home, rehabilitation centre or hospice after hospital discharge;
- suffering from cognitive impairment or diagnosed with dementia;
- legally incapacitated.

2.2.2 Randomization and blinding

Participants were randomly assigned to either the intervention or control group by means of permuted blocks of size four, stratified by gender and hospital department. Randomization was performed by an independent person using statistical software. As a final check and to ensure participants' safety, the actual treatment assignment was done by an independent dietitian. When participants continued in the home phase of the study they remained within the assigned treatment arm. Blinding was not possible as the product labels and hospital menu revealed whether products were protein-enriched. Therefore, both participants as well as researchers were aware of group assignment.

2.3 Nutritional intervention

Participants in the intervention group received a range of protein-enriched products with the look and taste of regular foods. These Cater with Care (CwC) products were specially developed in a collaboration between Wageningen University and various food and research companies, forming the Cater with Care consortium [16]. In general, the following products were available: bread, breakfast cereals, sweet and savoury snacks, mashed potatoes, meat, ice cream, dairy drinks, fruit beverages and soups.
The use of the CwC products was started within two days after hospital admission and continued until 12 weeks after hospital discharge. In the hospital phase participants received the CwC products in addition to the standard energy and protein rich hospital menu and in the home phase as part of their habitual diet. Participants were free to decide whether to use to CwC products in addition to or instead of standard products within their daily menu. For instance, a participant who chose to replace 2 slices of regular bread by the CwC bread had an additional intake of ± 5 grams of protein. Moreover, drinking a CwC fruit juice instead of a regular fruit juice increased protein intake with ± 10 grams. A complete overview on the products and their nutritional content can be found in Appendix I.

Participants allocated to the control group received the standard energy and protein rich diet during hospital stay. In the home phase, they were provided with regular non-protein-enriched variants of some of the CwC products, such as bread and dairy. Providing these products at home mainly served as an incentive to participate in the study. The use of proper placebo products with a low protein content did not seem ethical given the importance of an adequate protein intake during the recovery process. As some of the control products were naturally high in protein, such as milk, dairy desserts and snack meatballs, participants were still able to achieve a higher protein intake by adding these products to their daily menu. By doing so, a participant who for instance chose to consume a portion of 3 small meatballs as a snack in between meals increased protein intake with ± 20 grams. Appendix II contains an overview of the control products and their nutritional content.

The first 2 weeks after hospital discharge were meant to introduce participants in both groups to the complete assortment of CwC or control products for the home phase. Therefore, during this period participants were offered a standard package twice a week containing all variants of the different products. Subsequently, during the following 10 weeks participants received an ordering form through which they had a free choice in the type and amount of products they wanted to receive.

2.4 Study parameters

2.4.1 Protein intake

The primary outcome of this thesis was the mean protein intake expressed in grams per kilogram body weight per day (g/kg BW/day), assessed at week 2, 6 and 12 after hospital discharge. The aim was to find a between-group difference of at least 0,3 g/kg BW/day at week 12. Protein intake was assessed using a 24-h recall combined with a dietary food record, used as memory aid. Participants were asked to record their food intake including all meals, snacks and beverages during one pre-specified day. Trained students gave oral and written instructions about recording the type of foods consumed and estimating portion sizes in household measures. During a home visit on the following day, the 24-h recall was carried out by trained students in a face-to-face interview. During this interview the food records were checked for completeness and additional information was obtained about unclear items or amounts. An example of the dietary food record used can be found in Appendix III.

Data from the dietary food record were coded; including type and amount of food and time of consumption. Then, it was entered into the food-calculation programme Compl-eat (Human Nutrition, WUR, 2010-2015). Dietary protein as well as other macronutrient and total energy intake was calculated on the basis of the 2013 Dutch food composition database [35], which was incorporated in Compl-eat. Daily protein intake in grams per kilogram body weight per day (g/kg BW/day) was calculated for each individual participant using Excel. These calculations were performed with the use of ideal body weight (IBW). This was based on the assumption that fat free mass (FFM), and not whole body weight, is the true determinant of the protein requirement [36]. The use of IBW corrects for the relative decrease in FFM when BMI increases and the relative increase in FFM when body weight decreases [36]. For participants with a BMI > 27 kg/m^2 the IBW was based on a BMI of 27 kg/m^2, for participants with a BMI < 20 kg/m^2 the IBW was based on a BMI of 20,0 kg/m2 [36]. Body weight was adjusted using the following formulas: 27*height^2 and 20*height^2.

2.4.1.1. Relative contribution of different food groups and CwC products to total protein intake

For both the intervention and control group it was established which food groups contributed most to their total protein intake. In order to do so, all products consumed at week 2, 6 and 12 were obtained from food calculation programme Compl-eat and were classified into 17 different food groups corresponding to the EPIC-soft classification as used in the Dutch National Food Consumption Survey (VCP) older adults 2010-2012 [37]. At first, the absolute amount of protein in grams consumed per food group was calculated. Thereafter, the amount of protein consumed per food group was divided by the total amount of protein consumed, which resulted in the relative contribution of the different food groups expressed in percentages. Furthermore, for the intervention group it was calculated which percentage of the total protein intake was derived from the CwC products. Therefore, the absolute amount of protein consumed per CwC product category was calculated and divided by the total amount of protein consumed.

2.4.2 Functional status

The secondary outcome of this thesis was the change in functional status over the 12-week period after hospital discharge, assessed by the Barthel Index and the Short Physical Performance Battery.

2.4.2.1 Barthel index

The Collin and Wade-version of the Barthel Index (BI) was used to assess the level of independence in activities of daily living (ADL). This instrument contains ten items of which seven are related to basic ADL: grooming, toilet use, bladder control, bowel control, feeding, dressing and bathing, and three items related to mobility: transfer from bed to chair and vice versa, stair climbing and mobility at home. Participants were assessed on these items through a face-to-face interview conducted by trained students using the Dutch questionnaire version of the BI as developed by Post et al. [38].
For all items, except for bladder and bowel control, participants were asked to rate the level of assistance required in performing the activity during the past 24-48 hours. For the two items about bladder and bowel control participants were asked to what extent they had suffered from incontinence. A summary score between 0 and 20 was calculated by summing the scores of the ten items. In addition, the following cut-off values were used for score interpretation: 0-4: total dependence; 5-9: severe dependence; 10-14: participant needs some assistance but performs many activities on its own; 15-19: participant has a reasonable to well level of independence; 20: fully independent in ADL [38] [39]. The BI questionnaire used can be found in Appendix IV.

2.4.2.2 Short physical performance battery

The short physical performance battery (SPPB) was used to assess participants' physical performance. The SPPB consists of three components: balance, gait speed and chair rise time [29]. To assess balance, participants were asked to hold three increasingly difficult standing positions for 10 seconds each, starting with feet side by side, followed by a semi-tandem position and a final full-tandem position. Gait speed was assessed by letting participants walk a 4-meter course at their usual pace and recording their best performance (time in seconds) out of two attempts. If necessary, the use of walking aids such as a walking stick or a walker was allowed. For the chair-rise test, participants were asked to rise from and sit down in a chair five times without using their hands. The time in seconds for performing the five consecutive chair rises was recorded. All three components of the SPPB were categorized into a five-level score, with 0 indicating the inability to perform a test and 4 indicating the highest level of performance. Subsequently, a total performance score between 0 and 12 was calculated by summing up the scores of the three tests. Instructions for the tests and used scoring criteria can be found in Appendix V.

2.4.3 Other outcome measures

Body weight was measured using the same digital weighing scale (Seca Robusta 813) during each home visit. Participants were weighted while wearing indoor clothing and preferably without shoes. For logistical reasons it was not possible to assess a participant's body weight at the exact same moment of the day at the 2, 6 and 12-week measurements. Per session weight was measured two or three times and the calculated average weight was rounded to the nearest 0,01 kilogram (kg). Height was only assessed during the first measurement performed at the hospital using either a calibrated stadiometer or, if the participant could not stand, it was estimated using lower leg length. Measurements were rounded to nearest 0,1 cm. Body mass index (BMI) was calculated by dividing body weight (kg) by the square of the height (m).

Nutritional status was assessed at week 2, 6 and 12 using the full version of the Mini Nutritional Assessment (MNA) tool [40]. This is a validated 18-item instrument consisting of a screening and an assessment section. On the basis of questions regarding dietary intake and health status and anthropometric measurements (BMI, mid-upper arm circumference and calf circumference) a total score between 0 and 30 could be obtained. The following cut-off values were used: 24 - 30 points indicated a normal nutritional status, 17 - 23,5 points indicated a risk of malnutrition and < 17 points indicated malnutrition.

Information on participants' characteristics such as age, gender and reason for hospitalization (medical diagnosis) was obtained from an Excel file that was assembled and updated by the main study researcher. Furthermore, during the home visit at week 12, information was collected on daily assistance obtained through informal care ('mantelzorg'). In an additional questionnaire participants were asked the following question: *Do you receive daily assistance from an informal caregiver (for example a partner, child, friend or neighbour) in activities such as grocery shopping and meal preparation?*

2.5 Sample size calculation

Primary objective

A sample size calculation was performed using the primary objective of this thesis, which was to examine the effectiveness of the CwC products on increasing the protein intake of older adults to an intake of 1,2 - 1,5 g/kg BW/day during a 12-week period after hospital discharge. The desired effect size was calculated with the use of previous studies reporting mean daily protein intake levels of older adults admitted to the hospital or recently discharged from the hospital. The results of these studies are summarized in Appendix VI. Based on these results a current mean intake of 0,9 g/kg BW/day was used. The aim was to increase protein intake to the recommended level of 1,2 g/kg BW/day at week 12 after hospital discharge, resulting in a difference (D) of at least 0,3 g/kg BW/day. Based on the similarities in the intervention method, namely, the use of protein-enriched regular products, a within-group standard deviation (SD) of 0,3 g/kg BW/day as reported by Stelten and colleagues [10] was chosen for the sample size calculation. Calculations were performed using the following formula, where 'N' represents the number of participants per treatment arm:

$$n = \frac{2\sigma^2 (Z_\beta + Z_{\alpha/2})^2}{(d^*)^2} \qquad N = \frac{2*0.3^2\ (0.84 + 1.96)^2}{(0.3)^2}$$

At a power level of 80% and α of 5%, this resulted in a minimum requirement of 17 participants per treatment arm. When taking into account a 30% drop-out rate [11] a sample size of 23 participants per treatment group at the start of the home phase was considered to be adequate.

Secondary objective

Additional calculations were done for the secondary objective of this thesis, which was to assess whether using the CwC products resulted in a better functional status: either a greater change in Barthel Index (BI) score or Short Physical Performance Battery (SPPB) score in the three-month post-discharge period. To allow for a complete analysis of all the 2,6 and 12-week data before finishing this manuscript (June 2015) the total number of 34 participants, as calculated for the primary objective, seemed realistic. For this reason, a sample size of 17 participants per treatment group (N) was used to calculate the expected difference (D) that could be picked up in both the BI and the SPPB.
Unfortunately, no data were published on the standard deviation (SD) of change in BI scores over time in older adults receiving any form of nutritional supplementation. Therefore, it was decided to use data from a study that examined the effects of intensive and non-intensive home-based rehabilitation in stroke and hip fracture patients aged ≥ 65 years [41]. In this study, the largest reported SD of mean change from baseline to 12 weeks after hospital discharge was 2,1 points. Using this SD in the aforementioned formula, indicated that it would be possible to detect a true between-group difference in change not smaller than 2,1 points at a power level of 80% and α 5%. This is almost equal to the Minimal Clinically Important Difference (MCID) of 1,85 points as reported by Hsieh et al. [42]. To be able to pick this MCID at a power level of 80% and α 5%, a minimum of 21 participants per treatment group would be required.
In the study by Hsieh and colleagues, the MCID was established using an anchor-based method in a group of stroke rehabilitation patients. Participants rated their perceptions of the magnitude of change in ADL-

independence on a 15-point Likert-type scale. The MCID corresponded to the mean change in BI score of patients rating their independence level within the ranges of *a little better* to *somewhat better* and *a little worse* to *somewhat worse*. Because this MCID was established in stroke patients, additional information was searched on a relevant outcome in the BI score of older adults with other (chronic) medical conditions. This was done in literature and by consulting a geriatric physician from hospital Gelderse Vallei. However, as far as known, a clinically important or meaningful change in BI score has not yet been established for this population specifically.

The same method was applied for the Short Physical Performance Battery (SPPB). Again, calculations were based on sample size of 17 participants per treatment group. A standard deviation of change in SPPB score over time of 1,48 points was taken from a study by Perera and colleagues [43]. Calculations with the aforementioned formula indicated that it would be possible to detect a true between-group difference (D) in change not smaller than 1,5 points at a power level of 80% and α 5%. In contrast: to pick up the substantial meaningful change of 1,0 point difference in total SPPB score as reported by Perera et al. [43], a minimum of 35 participants per treatment group would be required.

2.6 Statistical analysis

Statistical analysis was performed using Excel software and SPSS statistics 22 (SPSS Inc, Chicago, IL). Statistical significance was set at alpha (α) 0,05. Data were analysed according to the intention-to-treat principle. This implies that all available data of the randomized participants were incorporated into the final analyses, regardless whether they had completed the full study. Prior to inclusion into the analyses all variables were examined for normality by means of a Shapiro-Wilk test and visual inspection (QQ-plot). Statistical differences in energy and protein intake between groups were analysed by independent samples T-test in case of normally distributed data or Mann-Whitney U test in case of a non-normal distribution. Statistical differences between proportions of participants achieving the recommended protein intake levels were analysed by Chi-square or Fisher's exact test. For the analysis of the BI and SPPB, only the total scores of both instruments were used. Prior to the statistical analyses the data were displayed in a column scatter in order to examine the distribution of the scores per group over the different time points. Since none of the data followed a normal distribution, between-group comparisons in BI and SPPB total scores were performed using a Mann-Whitney U test. A nonparametric Friedman's two-way analysis of variance (ANOVA) was used to test for significant differences in total scores within groups. In case of a statistical significant outcome on the Friedman's test, post-hoc analyses were performed. This was done using a Wilcoxon signed-rank test to make pairwise comparisons between the scores at the separate time points (week 2, 6 and 12). In order to correct for the multiple tests applied on the same data, a Bonferroni-correction was used and the alpha level was set at 0,017. Finally, the degree of association between the SPPB and BI was examined using correlation. In order to do so, all SPPB and BI total scores obtained by both groups at week 2, were used. Because of the small sample size and the non-normally distributed data, a nonparametric Spearman's rank-order correlation was used to determine the strength of the relationship.

3. Results

3.1 Study population

From October 2014 to April 2015 all elderly patients (≥ 65 years) admitted to the wards of Pulmonary medicine and Geriatric medicine of hospital Gelderse Vallei were screened for eligibility to participate in the CwC effect study. In order to finish this manuscript on time, the analysis for this thesis was restricted to the data from patients who were first admitted between October 2014 and the end of January 2015 at the latest. During this period, 91 patients who were enrolled in the hospital phase of the study were screened for eligibility to continue study participation in the home phase. A total of 38 subjects were excluded for the reasons described in Figure 2. In total, 53 participants were included in the home phase: 26 in the intervention group and 27 in the control group. For 13 participants the follow-up data were incomplete: in the intervention group 5 participants withdrew before the week-2 measurements and one participant was admitted to a hospice before having completed 12 study weeks. In the control group 5 participants withdrew before the week-2 measurements, one participant was admitted to a rehabilitation centre before week 6 and one participant died before study completion (week 12).

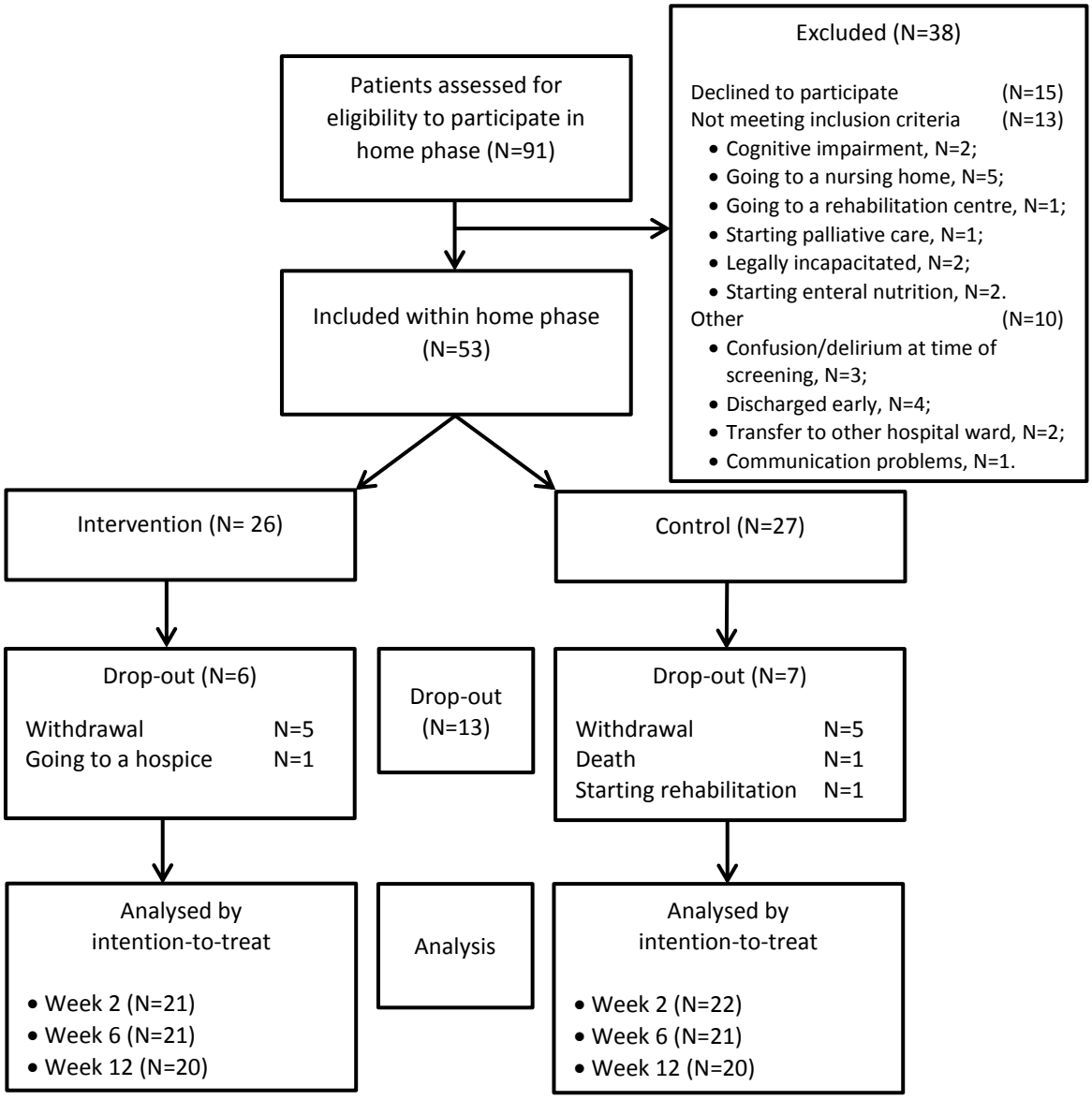

Figure 2: Flowchart of inclusion of participants in home phase CwC effect study.

The characteristics of the study population are presented in Table 1. These data reflect all included participants that finished the measurements at week 2 of the home phase (43 in total). Information on gender, age, ward of admission and medical diagnosis was collected during hospital stay. Body weight, Body Mass Index (BMI) and Mini Nutritional Assessment (MNA) score were obtained at week 2 and information on informal care at week 12. The mean age of the study population was 77,2 ± 7,1 years (range: 65 – 91 years) and 53% of the participants were female. In both groups the majority of participants were included from the ward of Pulmonary medicine and most suffered from an acute exacerbation of COPD. The results of the MNA show that none of the participants was malnourished and that most had a normal nutritional status at 2 weeks after hospital discharge. Median body weight of the control group was somewhat higher compared to the intervention group (76,60 kg vs. 70,70 kg). However, this difference almost disappeared (mean 70,80 kg vs. 69,12 kg) after adjusting body weight to ideal body weight (IBW) for participants with a BMI > 27 kg/m^2 or BMI < 20 kg/m^2. No other large differences in characteristics between the intervention and control group were observed.

Table 1. Characteristics of the study population. Information on gender, age, ward of admission and medical diagnosis was collected during hospital stay. Body weight, Body Mass Index (BMI) and Mini Nutritional Assessment (MNA) score were obtained at week 2 and information on informal care at week 12.

Characteristics	Total (N=43)	Control [a] (N=22)	Intervention[a] (N=21)
Female/Male, n	23/20	11/11	12/9
Age (y), mean ± SD	77,2 ± 7,1	78,4 ± 7,7	75,9 ± 6,3
Hospital ward, n (%)			
Pulmonary medicine	32 (74%)	16 (73%)	16 (76%)
Geriatric medicine	11 (26%)	6 (27%)	5 (24%)
Medical diagnosis in categories, n (%)			
Acute exacerbation COPD	23 (53%)	13 (59%)	10 (48%)
Upper respiratory infection/ pneumonia	8 (19%)	3 (14%)	5 (24%)
Other[b]	12 (28%)	6 (27%)	6 (28%)
Body weight (kg), median [IQR]	71,8 [64,8 – 84,1]	76,6 [66,3 – 84,1]	70,7 [64,3 – 85,6]
Adjusted body weight (kg), mean ± SD[c]	69,9 ± 9,1	70,8 ± 9,5	69,1 ± 8,9
BMI (kg/m^2), median [IQR][b]	26,7 [23,6 – 29,2]	27,1 [23,9 – 30,4]	26,4 [23,5 – 28,6]
MNA score, mean ± SD[d]	24,2 ± 2,7	24,4 ± 2,5	24,0 ± 2,9
MNA score in categories, n (%)			
< 17, malnourished	0 (0%)	0 (0%)	0 (0%)
17 – 23,5, at risk of malnutrition	16 (39%)	7 (33%)	9 (45%)
24 – 30, normal nutritional status	25 (61%)	14 (67%)	11 (55%)
Participants receiving informal care, n (%)	22 (54%)	11 (52%)	11 (55%)

[a] Missing values for body weight, BMI, MNA score and information on informal care for one participant in intervention group and one participant in control group.

[b] Category 'other' contains the following symptoms without a clear diagnosis: coughing and shortness of breath (N=3), gastrointestinal complaints (N=2), fever (N= 4) and generalized malaise (N=3).

[c] Body weight adjusted to ideal body weight (IBW) for participants with a BMI > 27 kg/m^2 or BMI < 20 kg/m^2.

[d] Mini Nutritional Assessment [40].

3.1.1 Body weight, BMI and MNA score during follow-up

The average body weight, BMI and MNA score at the separate time points were used to examine the progression of nutritional status over time in both groups. Body weight showed a non-normal distribution, and therefore medians [IQR] were calculated. The median body weight of the control group showed a decrease from 76,7 [66,3 – 84,1] in week 2 to 75,6 [66,9 – 84,9] in week 6 and 73,9 [68,0 – 83,9] in week 12. In contrast, the median weight of the intervention group increased from 70,7 [64,3 – 85,7] in week 2 to 72,5 [65,9 – 84,2] in week 6 and 74,4 [65,7 – 83,9] in week 12. However, these substantial weight changes did not correspond to the constant BMI and MNA scores seen in both groups (see Table 11 in Appendix VIII). To further clarify this unexpected and unexplained finding, also the mean (± SD) weights were calculated. These are displayed in Table 11 of Appendix VIII and Figure 3. When examining the means, the change in weight over time in both groups almost disappeared. The mean weight change between week 2 and 6 was 0,99 ± 1,37 in the control group compared to 0,31 ± 1,30 in the intervention group (P= 0,111). The mean weight change between week 6 and 12 was – 0,51 ± 2,33 for the control group compared to – 0,13 ± 2,19 for the intervention group (P= 0,601).

Figure 4 displays the mean body weight of both groups after adjusting the weight of participants with a BMI > 27 kg/m^2 or < 20 kg/m^2 to their ideal body weight (IBW). As seen in Figure 4, also the adjusted body weight remains constant in both groups. Next to that, the mean adjusted weight of the intervention and control group was comparable at the three different time points.

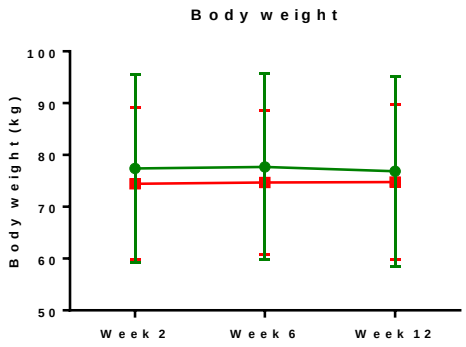

Figure 3: Average body weight (kg) of both groups at week 2, 6 and 12. Data represent mean ± SD.

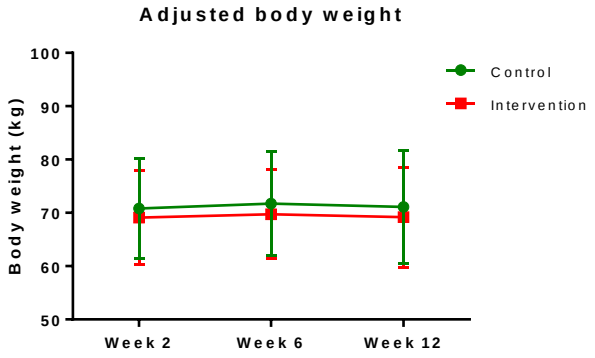

Figure 4: Average body weight adjusted to ideal body weight (IBW) for participants with a BMI > 27 kg/m^2 or BMI < 20 kg/m^2 in both groups, at week 2, 6 and 12. Data represent mean ± SD.

3.2 Protein intake

3.2.1 Daily protein intake at week 2, 6 and 12

Table 2 shows the mean protein intake expressed in grams per day (g/day) of both groups at week 2, 6 and 12. An independent samples T-test was used to compare the mean protein intake between groups. As shown in Table 2, the intervention group had a significantly higher mean daily protein intake at all three time points. In week 2 the mean intake was ± 42 grams higher (P<0,001) and in week 6 it was ± 43 grams higher (P= 0,002). In week 12 the mean difference had reduced to ± 29 grams, but remained highly significant (P= 0,014). Overall, the mean protein intake of the control group remained fairly constant over the different time points, whereas for the intervention group a decrease of 12 grams was seen between week 2 and 12.

Table 2. Daily protein intake of both groups in grams per day (g/day) at week 2, 6 and 12.

	Control	Intervention	Mean difference ± SE Difference	P-value
Week 2[a]	80,6 ± 20,1	122,5 ± 38,4	41,8 ± 9,6	<0,001*
Week 6[b]	77,4 ± 21,0	120,2 ± 51,5	42,9 ± 12,1	0,002*
Week 12[c]	81,1 ± 19,7	110,4 ± 43,4	28,9 ± 10,9	0,014*

Data are presented as mean ± standard deviation and were analysed with independent samples T-test.
*** p< 0,05 indicates significance.**
[a] Control (N=21) and Intervention (N=20).
[b] Control (N=21) and Intervention (N=21).
[c] Control (N=19) and Intervention (N=19).

The daily protein intake of both groups at week 2, 6 and 12 expressed in grams per kilogram body weight per day (g/kg BW/day) is presented in Table 3. A Shapiro-Wilk test that was applied prior to performing any additional statistical tests, showed a non-normal distribution of the data in the intervention group (see Table 5 in Appendix VII). Therefore, results are presented as median [IQR] and between-group comparisons were made with a nonparametric test (Mann-Whitney U). Because the objective of this thesis was formulated in terms of comparing the mean protein intake per group (not median), Table 3 also indicates the mean and SD of the intake in g/kg BW/day. The results in Table 3 reveal a significant difference in the protein intake of both groups at all three time points. The intervention group had a higher mean protein intake level compared to control group. At week 2 and 6 the difference was 0,6 g/kg BW/day and at week 12 it was 0,4 g/kg BW/day.

Table 3. Daily protein intake of both groups in grams per kilogram body weight per day (g/kg BW/day) at week 2, 6 and 12.

	Control		Intervention		P-value
	Median [IQR]	**Mean ± SD**	**Median [IQR]**	**Mean ± SD**	
Week 2[a]	1,2 [0,9 – 1,3]	1,2 ± 0,3	1,8 [1,3 – 1,9]	1,8 ± 0,6	<0,001*
Week 6[b]	1,0 [0,8 – 1,4]	1,1 ± 0,4	1,6 [1,3 – 2,0]	1,7 ± 0,8	0,001*
Week 12[c]	1,1 [0,9 – 1,4]	1,2 ± 0,3	1,5 [1,1 – 1,8]	1,6 ± 0,7	0,020*

Data are presented as median [IQR] and mean ± SD and were analysed with Mann-Whitney U test.
*** p< 0,05 indicates significance.**
[a] Control (N=21) and Intervention (N=20).
[b] Control (N=21) and Intervention (N=21).
[c] Control (N=19) and Intervention (N=19).

3.2.2 Daily protein intake levels compared to the recommendations

Figure 5 displays the distribution of the protein intake in grams per kilogram body weight per day (g/kg BW/day) of participants in both groups at the three different measurement moments. The current recommended intake level (RDA) of 0,8 g/kg BW/day as well as the intake levels of 1,2 – 1,5 g/kg BW/day, as recommended by the PROT-AGE group, are highlighted within the graphs. For both groups it was calculated which percentage of the participants achieved the recommended intake levels. Subsequently, a Chi-square or Fisher's exact test was used to compare these proportions between groups. The results of these tests are presented in Table 12 and 13 in Appendix IX.

At week 2 all participants in the intervention group achieved the RDA of 0,8 g/kg BW/day, whereas 3 participants in the control group failed to meet this intake level (P= 0,232). Furthermore, all but two participants (90%) in the intervention group had a protein intake of 1,2 g/kg BW/day compared to 11 participants (52%) in the control group (P= 0,008). The intake level of 1,5 g/kg BW/day was achieved by 13 participants in the intervention group (65%) compared to only 3 (14%) in the control group (P=0,001).

In week 6, the protein intake of the intervention group showed a greater variability compared two week 2, with intake levels ranging between 0,47 g/kg BW/day and 3,90 g/kg BW/day. One of the participants in the intervention group was not able to meet the RDA of 0,8 g/kg BW/day compared to 4 in the control group (P= 0,343). Overall, the proportion of participants achieving the intake level of 1,2 g/kg BW/day remained significantly higher in the intervention group (81%) compared to the control group (38%) (P= 0,005). The same result was found for the intake level of 1,5 g/kg BW/day, which was achieved by 15 participants in the intervention group (71%) compared to 3 (14%) in the control group (P<0,001).

In week 12 the number of participants in the intervention group with an intake level of 1,2 g/kg BW/day had reduced to 14 (74%) compared to an unchanged number of 8 participants (42%) in the control group. A borderline significant difference in proportions was found (P= 0,045). Moreover, 10 participants (53%) in the intervention group were able to achieve the intake level of 1,5 g/kg BW/day compared to 3 participants (16%) in the control group (P= 0,017).

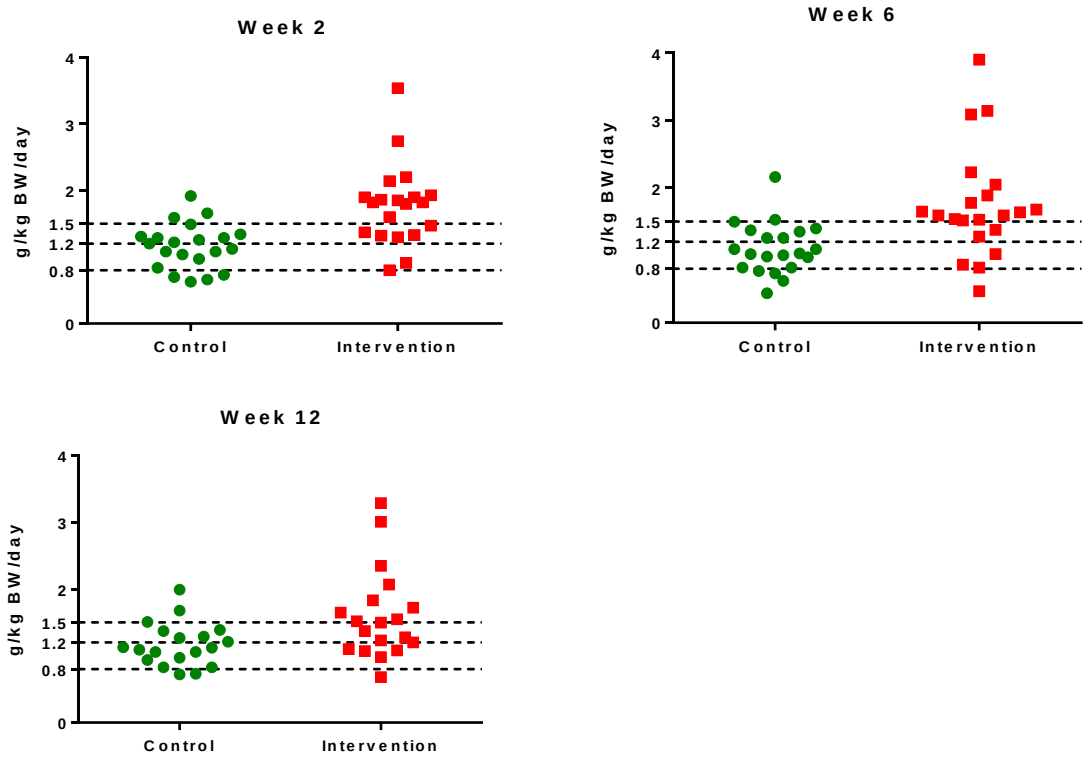

Figure 5: Total daily protein intake (g/kg BW/day) of participants in both groups compared to the recommended intake levels.

3.2.3 Relative contribution of different food groups to the total protein intake

The three food groups contributing most to the total protein intake of both groups at the different time points were 'Dairy products', 'Meat and meat products' and 'Cereals and cereal products'. There was a slight variation in the level of contribution of these food groups per treatment group and per week, but on average 'Dairy products' were responsible for 30%, 'Meat and meat products' for 25% and 'Cereals and cereal products' for 18% of the total protein intake. Overall, the food groups 'Legumes' and 'Sugar and confectionery' contributed the least to the total protein intake (no more than 1%). Differences between groups were seen for the level of contribution of 'Non-alcoholic beverages' and 'Soups, bouillon'. In the control group these foods contributed no more than 4% to the total protein intake, whereas in the intervention group this was up to 10%. This difference is most likely explained by the presence of CwC alternatives within these food groups. A complete overview on the relative contribution of the different food groups to the total protein intake of both groups can be found in Appendix X.

3.2.4 Relative contribution of the Cater with Care products to the total protein intake

Figure 6 displays the relative contribution of the CwC products to the total protein intake of the intervention group at week 2, 6 and 12. The CwC products accounted for 62% of the total protein intake of the intervention group at week 2, 59% in week 6 and 48% in week 12. At all three time points, 'Bread' and 'Dairy desserts' contributed most to the total protein intake, followed by 'Meat' and 'Fruit beverages'. In week 12 the 'Fruit beverages' contributed more (9%) to the total protein intake than 'Meat' (6%). Both 'Mashed potatoes' as well as 'Ice cream' did not contribute to the total protein intake at week 2, 6 and 12 and therefore are not displayed in the graphs. Over the weeks the largest reduction in the relative contribution was seen for 'Meat' and 'Dairy beverages', whereas the contribution of 'Bread', 'Fruit beverages', 'Breakfast cereals' and 'Soups' remained almost constant.

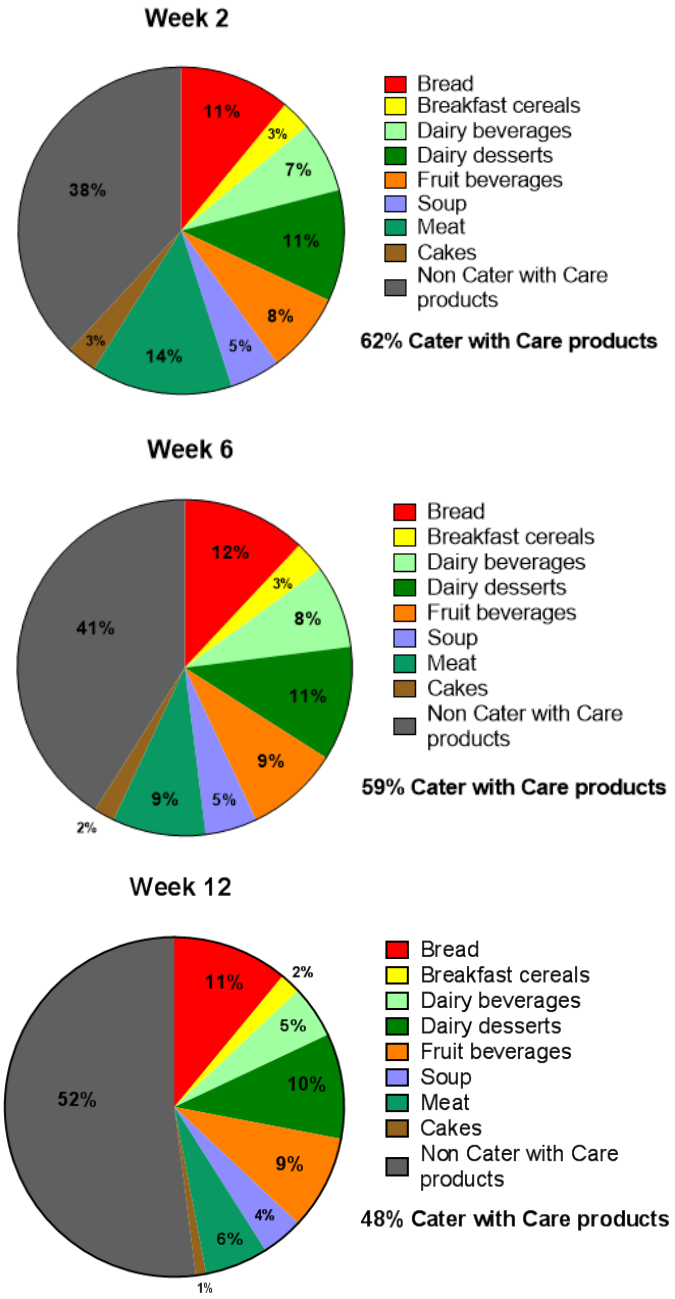

Figure 6: Relative contribution of the Cater with Care products to the total protein intake of the intervention group at week 2, 6 and 12.

3.3 Daily energy intake at week 2, 6 and 12

Table 4 shows the mean energy intake (kcal/day) as well as the percentage of energy derived from protein in both groups at week 2, 6 and 12. The results indicate a substantially higher mean energy intake in the intervention group at all three time points, although no statistically significant differences between groups were found. As shown in Table 4 the higher energy intake of the intervention group is mostly explained by the higher protein intake (protein energy percentage (En%). A significant mean difference of 5 - 6 En% was found between the groups in week 2 and 6 and a non-significant difference of 2 En% in week 12. These results are in line with the previously reported higher mean protein intake (g/day) of the intervention group as compared to the control group (Section 3.2.1).

In week 2, there were three participants with a protein intake above the tolerable upper intake level (UL) of 25 En% [44], against none of the participants in the control group (P= 0,107). Also in week 6, the intake of four participants in the intervention group exceeded the UL, against none in the control group (P= 0,107). In week 12, there were two participants in the intervention group and one in the control group with a protein intake above the UL (P= 1,000).

As for the other macronutrients: a slightly higher (non-significant) carbohydrate intake was seen in the intervention group at week 2 and 12. The mean difference (± SEM) in carbohydrate intake was 22,1 grams (± 24,3 g) in week 2 and 19,8 grams (± 22,2 g) in week 12. No differences were found for fat intake, apart from a 10,4 grams (± 11,3 g) higher intake in the intervention group at week 12 (p= 0,363).

Table 4. Total daily energy intake (kcal/day) and percentage of energy derived from protein (En%) at week 2, 6 and 12.

	Control	Intervention	Mean difference ± SE Difference	P-value
Energy intake (kcal/day)				
Week 2[a]	2050 ± 500	2354 ± 712	304 ± 191	0,120
Week 6[b]	1957 ± 471	2188 ± 810	231 ± 204	0,265
Week 12[c]	1973 ± 561	2250 ± 609	276 ± 190	0,154
Percentage of energy from protein (En%)				
Week 2[a]	15,9 ± 2,3	21,0 ± 4,2	5,1 ± 1,0	<0,001
Week 6[b]	16,0 ± 3,2	22,0 ± 4,5	6,0 ± 1,2	<0,001
Week 12[c]	17,1 ± 4,1	19,5 ± 5,2	2,4 ± 1,5	0,129

Data are presented as mean ± standard deviation and were analysed with independent samples T-test.
[a] Week 2: Control (N=21) and Intervention (N=20).
[b] Week 6: Control (N=21) and Intervention (N=21).
[c] Week 12: Control (N=19) and Intervention (N=19).

3.3.1 Oral nutritional supplements

Two participants in both groups reported the use of oral nutritional supplements (ONS) during the study period. The total amount of energy obtained from ONS by the two participants in the intervention group was 1450 kcal/day in week 2, 1200 kcal/day in week 6 and 1150 kcal/day in week 12.

The two participants in the control group obtained a total of 300 kcal/day in week 2 and 600 kcal/day in week 12. None of the participants in the control group reported the use of ONS in week 6.

Exclusion of these participants from the analyses did not change the significant differences found in mean protein intake (g/day) at any of the time points (see Table 14 in Appendix XI). However, a slight reduction of 35 kcal/day was seen in the mean difference in energy intake (kcal/day) at week 6 and a reduction of 43 kcal/day in week 12. The mean differences in energy intake between groups remained non-significant at all three time points (see Table 15 in Appendix XI).

3.4 Functional status

3.4.1 Barthel Index

The distribution of the Barthel Index (BI) total scores per group at the different time points is displayed in Figure 7. A Shapiro-Wilk test indicated that none of the scores in both groups followed a normal distribution (see Table 7 in Appendix VII). Therefore, the results in Table 5 are presented as median [IQR] and between-group comparisons were made with a nonparametric test (Mann-Whitney U). As shown in Table 5 and Figure 7, the median scores of both groups range between 16 and 19 at all three measurement moments. This indicates a reasonable to well level of ADL independence within the study population [38] [39]. Moreover, there appeared to be no large differences in median scores between groups at any moment. The P-values derived by a Mann-Whitney U test also indicated no significant differences between groups.

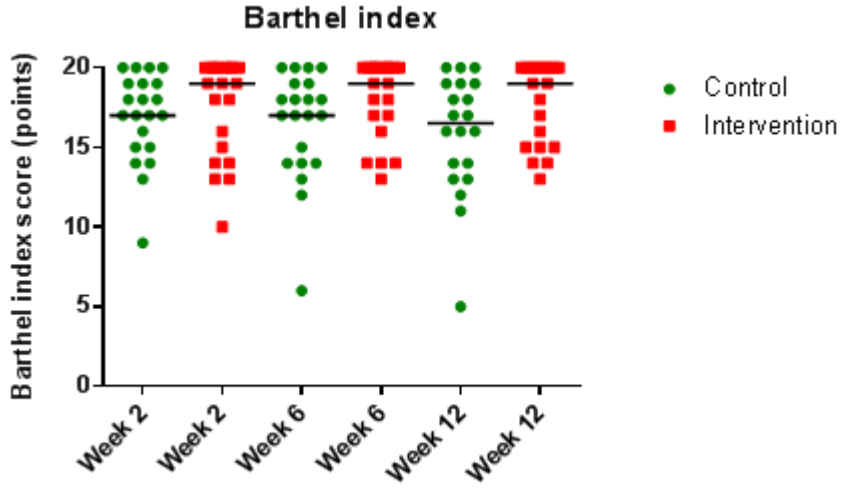

Figure 7: Distribution of the BI total scores within both groups at week 2, 6 and 12. Black bars represent median BI total scores per group.

Table 5. Median Barthel index (BI) total scores of both groups at week 2, 6 and 12.

	Control	Intervention	P-value
	Median [IQR]	**Median [IQR]**	
Week 2[a]	17 [15 – 19]	19 [14 – 20]	0,353
Week 6[b]	17 [14 – 19]	19 [17 – 20]	0,078
Week 12[c]	16 [13 – 19]	19 [15 – 20]	0,158

Data are presented as median [IQR] and mean ± SD. Analysis was performed with a Mann-Whitney U test.
[a] Week 2: Control (N=21) and Intervention (N=20).
[b] Week 6: Control (N=21) and Intervention (N=21).
[c] Week 12: Control (N=19) and Intervention (N=20).

As seen in Table 5 and Figure 7, the median scores of the intervention group remained constant, whereas a small decrease occurred in the scores of the control group. A Friedman's two-way analysis of variance (ANOVA) was used to test for a significant change in BI scores over time within the groups.
No significant differences were found between the scores at the different time points within the intervention groups (P= 0,150). However, the Friedman's test did indicate a significant difference in scores within the control group (P= 0,010). To further clarify this finding, also the mean (instead of median) total scores per group and per week were calculated, but these were not tested for significant differences due to the skewed distributions. The results are presented in Table 6. Indeed, also the mean scores indicated a reduction in score for the control group but not for the intervention group.

After examination of the column scatter in Figure 7 it was suspected that the decreasing score of the control group was highly influenced by the (decreasing) outlier. As expected, excluding this participant from the analyses caused the mean score of the control group to increase from 16,9 ± 2,8 to 17,3 ± 2,2 in week 2, 16,5 ± 3,4 to 17,0 ± 2,5 in week 6 and from 15,7 ± 3,8 to 16,2 ± 2,8 in week 12. The median scores did not change. Moreover, still a significant within-group difference was found between the scores at the separate time points as indicated by the Friedman's two-way ANOVA (P= 0,022).
Therefore, post-hoc analyses were performed with a Wilcoxon signed-rank test to determine between which time points the difference in scores occurred within the control group. To account for the multiple tests applied on the same data, a Bonferroni-correction was used. The level of significance (α: 0,05) was divided by the number of comparisons made (three) and set at α: 0,017. There were no significant differences between the BI scores at week 2 and 6 (P= 0,036), between week 6 and 12 (P= 0,210) and between week 2 and 12 (P= 0,022) within the control group. This is despite the overall (1 point) decrease observed in median and mean BI score of the control group between week 2 and 12.

Table 6. Mean Barthel index (BI) total scores of both groups at week 2, 6 and 12.

	Control	**Intervention**
	Mean ± SD	**Mean ± SD**
Week 2[a]	16,9 ± 2,8	17,4 ± 3,1
Week 6[b]	16,5 ± 3,4	18,0 ± 2,5
Week 12[c]	15,7 ± 3,8	17,7 ± 2,6

Data are presented as mean ± SD. Means were not tested for significant differences between groups.
[a] Week 2: Control (N=21) and Intervention (N=20).
[b] Week 6: Control (N=21) and Intervention (N=21).
[c] Week 12: Control (N=19) and Intervention (N=20).

In addition, it was examined whether there was a significant difference in change in BI scores between intervention and control group. In order to do so, the difference in BI score between the separate time points (week 2 – week 6, week 2 – week 12 and week 6 – week 12) was calculated for each participant in both groups. A subsequent Mann-Whitney U test indicated no significant differences in the changes between groups at a decreased significance level of α: 0,017 (see Table 16 in Appendix XII).

3.4.2 Short Physical Performance Battery

Figure 8 displays the results of the Short Physical Performance Battery (SPPB) total scores of both the intervention and control group over the different time points. Apart from the scores of the control group at week 2 and 6, none of the data were normally distributed (see Table 9 in Appendix VII). Therefore, results in Table 7 are presented as median [IQR]. The median SPPB scores of both groups were almost equal at all three time points. The P-values derived by a Mann-Whitney U test also indicated no significant differences between groups.

The results in Figure 8 and Table 7 suggest a slight increase in SPPB score over time in both groups. Therefore, also here a Friedman's two-way ANOVA was used to test for differences in SPPB scores over time within groups. Despite the observed increase in median scores, no significant difference between the scores at the different time points were found for either the intervention (P= 0,439) or control group (P= 0,368). Because (visually) still a small increase in score seemed to occur within both groups (although not significant), it was decided to further examine this observation. This was done by calculating the difference in SPPB total score between the separate time points for each individual participant. Since none of these changes followed a normal distribution, results were displayed as median [IQR]. As seen in Table 17 in Appendix XII, all median changes in SPPB total score were equal to zero.
For a better interpretation of these results, also the mean changes in SPPB total score were calculated, but these were not tested for significant differences due to the skewed distribution. As shown in Table 17 in Appendix XII, also the mean changes were close to zero. A subsequent Mann-Whitney U test indicated no significant differences in changes between groups at a decreased alpha-level of 0,017.

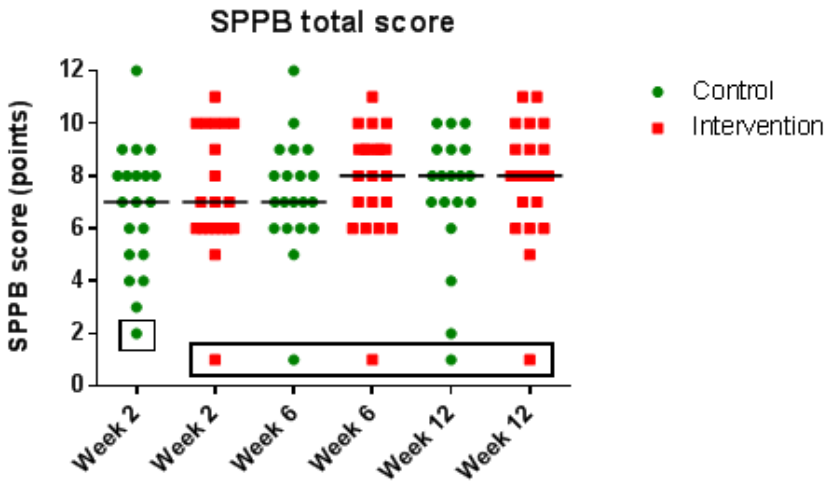

Figure 8: Distribution of the SPPB total scores within both groups at week 2, 6 and 12. Black bars represent the median SPPB total score per group. Black frames mark participants with very low SPPB total scores (≤2 points) that were (post-hoc) removed from the analyses.

Table 7. Median SPPB total scores of both groups at week 2, 6 and 12.

	Control	Intervention	P-value
	Median [IQR]	**Median [IQR]**	
Week 2[a]	7,0 [4,5 – 8,0]	7,0 [6,5 – 10,0]	0,099
Week 6[b]	7,0 [6,0 – 8,5]	8,0 [6,5 – 9,0]	0,160
Week 12[c]	8,0 [7,0 – 9,0]	8,0 [6,2 – 9,7]	0,531

Data are presented as median [IQR] and were analysed with Mann-Whitney U test.
[a] Control (N=20), Intervention (N=20).
[b] Control (N=21), Intervention (N=21).
[c] Control (N=19), Intervention (N=20).

Finally, as seen in the column scatter of Figure 8, there were two participants (one in each group) with a very low SPPB total score (≤ 2 points) at all three time points. It was decided to (post-hoc) remove these participants from the analyses to examine their influence on the median SPPB total scores at the separate time points, as well as the change in scores occurring within groups.

After exclusion of the participants, the week 6 and week 12 data of the intervention group showed a normal distribution. However, this was not the case for the week 2 data of the intervention group and the week 6 and 12 data of the control group. Furthermore, a very small increase in the median scores was observed for the intervention group at week 2 and 6: the median score at week 2 increased from 7,0 [6,5 – 10,0] to 7,5 [7,0 – 10,0] and the score at week 6 increased from 8,0 [6,5 – 9,0] to 8,5 [7,0 – 9,0]. The median scores of the control remained constant. Furthermore, still no significant between-group differences were found for the median scores at the separate time points (Mann-Whitney U test). Next to that, a Friedman's two-way ANOVA also indicated no significant differences in SPPB scores over time within groups.

3.4.3 Association between Barthel Index and Short Physical Performance Battery

The scatterplot in Figure 9 displays the relationship between the SPPB total score and BI total score obtained by the participants in both groups at week 2. As seen in the graph, there appeared to be no linear relationship. Moreover, none of the participants had a BI total score of < 10, while the scores obtained on the SPPB occurred across the entire range of the instrument (1 - 12). Despite this, the Spearman's rank-order test indicated a moderate to strong positive correlation between the SPPB total score and BI total score, which was highly statistically significant (r_s: 0,599, P: <0,001).

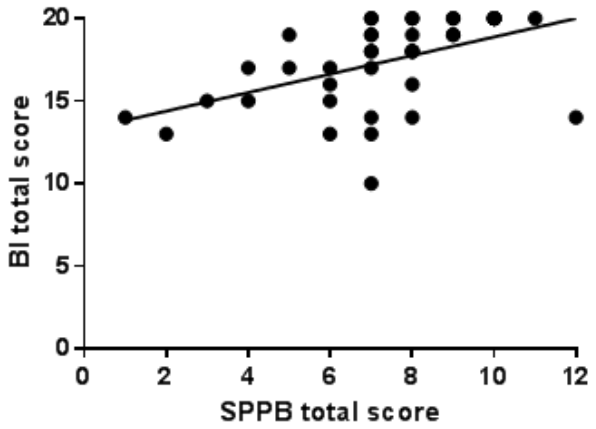

Figure 9: Scatterplot showing the relationship between the SPPB total score and BI total score obtained by participants at week 2. Spearman's rank-order test indicated a statistically significant moderate to strong positive correlation (r_s: 0,599, P: <0,001).

4. Discussion and conclusion

The results of this thesis show that the use of a variety of protein-enriched Cater with Care (CwC) products significantly increases the total daily protein intake of older individuals recently discharged from the hospital. One of the most important strengths of this study was that the large majority of participants in the intervention group was able to achieve at least the minimum intake level of 1,2 g/kg BW/day as recommended by the PROT-AGE group [8]. On average, 82% of participants in the intervention group achieved this intake level, against 48% of the controls. Furthermore, the higher protein intake was achieved without actively stimulating participants to use the CwC products. Instead, participants were free to choose the type and amount of products they wanted to consume. We believe that this is the best approach to enhance compliance to the products. Another important strength of this study is its randomized controlled trial design with statistical analyses performed according to the intention-to-treat principle. Since randomization occurred shortly after hospital admission and not all participants continued to the home phase of the study, there was a risk that randomization would not hold. However, the population characteristics described in this thesis, indicate that the groups were still comparable at the start of the home phase. A final strength of this study is that we not only assessed the effect on protein intake, as was done by two recent comparable studies [10, 45], but also included relevant outcome measures on physical function. One of these measures provided information on participants' level of independence in ADL and thereby has a direct association with quality of life [7].

In this thesis, we aimed to find a between-group difference in protein intake of 0,3 g/kg BW/day at the end of the study period. However, a striking mean difference of 0,6 g/kg BW/day was already observed at two weeks after hospital discharge, and after twelve weeks this was still 0,4 g/kg BW/day. These differences in mean intake are a positive finding, especially when considering the relatively high mean protein intake of the control group. The high protein intake of the controls was a surprising observation in the current thesis. It most likely reflects the fact that participants were aware of the importance of a sufficient protein intake, since they received a protein rich menu and written dietary advice during hospitalisation. We believe that this caused them to increase the consumption of products that are naturally high in protein.

Our results on protein intake are positive when compared to a similar study by Stelten et al. [10]. In this study, performed in a hospital setting, only 36% of participants in the intervention group achieved the intake level of 1,2 g/kg BW/day, against 8% of the controls. However, Stelten and colleagues only used protein-enriched bread and drinking yoghurt. We therefore believe that the use of a larger variety of products in the current study is an important explanation for the much higher proportion found.

However, not all products appeared to be suitable to provide protein supplementation, as indicated by their low relative contribution to the total protein intake. Moreover, during the three months of follow-up we observed a 14% reduction in the relative contribution of the CwC products. This indicates a lower compliance to the products when used over a longer period of time. A reassuring finding was that the use of the CwC products did not cause the participants to consume less from other meal components, as is reflected by their non-significant but substantially higher mean energy intake. This is despite the regularly reported strong satiating effects of dietary proteins [12, 46]. Moreover, body weight, BMI and MNA score remained constant in both groups, which indicates a stable nutritional status over time.

Despite the positive findings on protein intake, our results do not indicate that continuing the use of the CwC products after hospital discharge, improves the functional recovery of older individuals. None of the groups showed an improvement in the level of independence in activities of daily living (ADL), as measured by the Barthel Index (BI). Instead, we observed a small (1 point) decrease in the BI score of the control group, whereas the score of the intervention group remained constant. This may indicate that the use of the CwC products in addition to a standard diet is an effective approach to maintain physical function of older individuals. However, this finding should be interpreted with caution since the preliminary analyses lacked power to find a statistically significant effect. Our results are in line with previous studies who also reported no significant improvement in the BI score of older individuals using dietary protein supplementation [20] [21] [22].

Also for lower-extremity physical performance, as measured by the Short Physical Performance Battery (SPPB), we found no significant differences between groups. Both groups showed a very small non-significant improvement in SPPB score over time, which indicates that at least some improvement in physical performance occurs after hospital discharge, but this is not influenced by a higher protein intake. It is possible that a longer intervention period might have resulted in larger effects, since for instance Tieland et al. [33] found a significant 1 point increase in the SPPB score of frail older adults after 24 weeks of protein supplementation. The same holds for ADL: in one of the few studies that did report a significant improvement in the BI score of older individuals using protein supplementation, the effect occurred only after 24 weeks [23]. Next to that, the relatively high BI score observed within our population, indicates that participants already had a reasonable to well level of ADL independence [38] [39]. We therefore believe a ceiling-effect may have occurred.

The use of both the Barthel Index as well as the Short Physical Performance Battery within the current thesis was chosen on the basis of previous studies [27, 30]. These studies concluded that the combination of a self-report and a performance-based measure allows to obtain a more complete overview on functional status. The results of this thesis indicate a relatively strong and highly significant correlation between the two measures on a group level, but not on the individual level.

The results of this study should be interpreted in the light of some limitations. The first one is its non-blinded design. Blinding of participants and researchers was not possible since product labels revealed whether products were protein-enriched. Since participants were aware of group assignment and knew about the goal of the study, it can be questioned whether this has influenced our results found on protein intake. For example, participants in the intervention group may have over reported their use of the CwC products, resulting in a higher protein intake than what was actually consumed. However, if this was the case, we believe that the between-group differences in mean intake would be larger than those found in the current thesis. Instead, the control group had a surprising high mean protein intake as compared to what was expected on the basis of previous studies. This indicates that, if overreporting on protein intake occurred, this happened in similar amount in both groups. Furthermore, any possible overreporting on protein intake within the control group did not interfere with the proposed intervention effect, since the observed difference in mean intake still exceeds the goal of 0,3 g/kg BW/day at all three time points.

A second limitation is that the measurements of participants were performed by different students, which may have led to a large inter-observer variability. Training sessions were arranged to ensure that all students knew how to perform the measurements and how to properly handle study equipment. Furthermore, since each student measured participants in both groups, systematic errors and bias are unlikely. A third limitation of this study is that we did not examine the effect of physical training. Apart from an adequate protein intake also regular (resistance-type) exercise has been shown to be beneficial for muscle mass and function of older adults [8, 47]. Therefore, for future studies it would be of interest to examine whether functional status of older adults could possibly improve more when combining the use of the CwC products with physical training.

In conclusion, these preliminary results of the CwC effect study indicate that supplementing a standard home-based diet with a variety of CwC products is an effective approach for older individuals to achieve the proposed recommended protein intake level of 1,2 – 1,5 g/kg BW/day. Moreover, from the current results it appears that starting the use of the CwC products in the hospital and continuing to use them after discharge, might help to maintain rather than improve functional status of older individuals. However, due to the lack of power with the current sample size, this finding should be confirmed in the final analysis of the effect study.

References

1. Giesbers, H., A. Verweij, and J.d. de Beer. *Vergrijzing samengevat. In: Volksgezondheid Toekomst Verkenning, Nationaal Kompas Volksgezondheid. Bilthoven: RIVM*. 2013 [cited 2015 January 12]; Available from: http://www.nationaalkompas.nl/bevolking/vergrijzing/vergrijzing-samengevat/.
2. Inzitari, M., et al., *Nutrition in the age-related disablement process.* J Nutr Health Aging, 2011. **15**(8): p. 599-604.
3. Health Council of the Netherlands, *Undernutrition in the elderly. The Hague: Health Council of the Netherlands, 2011; publication no. 2011/32*. 2011.
4. Norman, K., et al., *Prognostic impact of disease-related malnutrition.* Clin Nutr, 2008. **27**(1): p. 5-15.
5. Morley, J.E., *Sarcopenia in the elderly.* Fam Pract, 2012. **29 Suppl 1**: p. i44-i48.
6. Cruz-Jentoft, A.J., et al., *Sarcopenia: European consensus on definition and diagnosis: Report of the European Working Group on Sarcopenia in Older People.* Age Ageing, 2010. **39**(4): p. 412-23.
7. Rizzoli, R., et al., *Quality of life in sarcopenia and frailty.* Calcif Tissue Int, 2013. **93**(2): p. 101-20.
8. Bauer, J., et al., *Evidence-based recommendations for optimal dietary protein intake in older people: a position paper from the PROT-AGE Study Group.* J Am Med Dir Assoc, 2013. **14**(8): p. 542-59.
9. Wolfe, R.R., S.L. Miller, and K.B. Miller, *Optimal protein intake in the elderly.* Clin Nutr, 2008. **27**(5): p. 675-84.
10. Stelten, S., et al., *Protein-enriched 'regular products' and their effect on protein intake in acute hospitalized older adults; a randomized controlled trial.* Clin Nutr, 2014.
11. Neelemaat, F., et al., *Post-discharge nutritional support in malnourished elderly individuals improves functional limitations.* J Am Med Dir Assoc, 2011. **12**(4): p. 295-301.
12. Nieuwenhuizen, W.F., et al., *Older adults and patients in need of nutritional support: review of current treatment options and factors influencing nutritional intake.* Clin Nutr, 2010. **29**(2): p. 160-9.
13. Morley, J.E., *Decreased food intake with aging.* J Gerontol A Biol Sci Med Sci, 2001. **56 Spec No 2**: p. 81-8.
14. Volkert, D., et al., *ESPEN Guidelines on Enteral Nutrition: Geriatrics.* Clin Nutr, 2006. **25**(2): p. 330-60.
15. Milne, A.C., et al., *Protein and energy supplementation in elderly people at risk from malnutrition.* Cochrane Database Syst Rev, 2009(2): p. CD003288.
16. Cater with Care. *Cater with Care*. 2012; Available from: http://www.caterwithcare.nl/.
17. Neelemaat, F., et al., *Oral nutritional support in malnourished elderly decreases functional limitations with no extra costs.* Clin Nutr, 2012. **31**(2): p. 183-90.
18. Mahoney, F.I. and D.W. Barthel, *Functional Evaluation: The Barthel Index.* Md State Med J, 1965. **14**: p. 61-5.
19. Hartigan, I., *A comparative review of the Katz ADL and the Barthel Index in assessing the activities of daily living of older people.* Int J Older People Nurs, 2007. **2**(3): p. 204-12.
20. McMurdo, M.E., et al., *Should oral nutritional supplementation be given to undernourished older people upon hospital discharge? A controlled trial.* J Am Geriatr Soc, 2009. **57**(12): p. 2239-45.
21. Wouters-Wesseling, W., et al., *Study of the effect of a liquid nutrition supplement on the nutritional status of psycho-geriatric nursing home patients.* Eur J Clin Nutr, 2002. **56**(3): p. 245-51.
22. Smoliner, C., et al., *Effects of food fortification on nutritional and functional status in frail elderly nursing home residents at risk of malnutrition.* Nutrition, 2008. **24**(11-12): p. 1139-44.
23. Lee, L.C., A.C. Tsai, and J.Y. Wang, *Need-based nutritional intervention is effective in improving handgrip strength and Barthel Index scores of older people living in a nursing home: A randomized controlled trial.* Int J Nurs Stud, 2015.
24. de Morton, N.A., J.L. Keating, and M. Davidson, *Rasch analysis of the barthel index in the assessment of hospitalized older patients after admission for an acute medical condition.* Arch Phys Med Rehabil, 2008. **89**(4): p. 641-7.

25. Quinn, T.J., P. Langhorne, and D.J. Stott, *Barthel index for stroke trials: development, properties, and application.* Stroke, 2011. **42**(4): p. 1146-51.
26. Brach, J.S., et al., *Identifying early decline of physical function in community-dwelling older women: performance-based and self-report measures.* Phys Ther, 2002. **82**(4): p. 320-8.
27. Reuben, D.B., et al., *Refining the categorization of physical functional status: the added value of combining self-reported and performance-based measures.* J Gerontol A Biol Sci Med Sci, 2004. **59**(10): p. 1056-61.
28. Hoeymans, N., et al., *Measuring functional status: cross-sectional and longitudinal associations between performance and self-report (Zutphen Elderly Study 1990-1993).* J Clin Epidemiol, 1996. **49**(10): p. 1103-10.
29. Guralnik, J.M., et al., *A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission.* J Gerontol, 1994. **49**(2): p. M85-94.
30. Latham, N.K., et al., *Performance-based or self-report measures of physical function: which should be used in clinical trials of hip fracture patients?* Arch Phys Med Rehabil, 2008. **89**(11): p. 2146-55.
31. Volpato, S., et al., *Predictive value of the Short Physical Performance Battery following hospitalization in older patients.* J Gerontol A Biol Sci Med Sci, 2011. **66**(1): p. 89-96.
32. Ostir, G.V., et al., *Reliability and sensitivity to change assessed for a summary measure of lower body function: results from the Women's Health and Aging Study.* J Clin Epidemiol, 2002. **55**(9): p. 916-21.
33. Tieland, M., et al., *Protein supplementation improves physical performance in frail elderly people: a randomized, double-blind, placebo-controlled trial.* J Am Med Dir Assoc, 2012. **13**(8): p. 720-6.
34. Kim, C.O. and K.R. Lee, *Preventive effect of protein-energy supplementation on the functional decline of frail older adults with low socioeconomic status: a community-based randomized controlled study.* J Gerontol A Biol Sci Med Sci, 2013. **68**(3): p. 309-16.
35. National Institute for Public Health and the Environment (RIVM). *NEVO-online versie 2013/4.0, RIVM, Bilthoven, 2013*. Available from: http://nevo-online.rivm.nl/.
36. Weijs, P.J., H.P. Sauerwein, and J. Kondrup, *Protein recommendations in the ICU: g protein/kg body weight - which body weight for underweight and obese patients?* Clin Nutr, 2012. **31**(5): p. 774-5.
37. Ocke MC, B.-R.E., de Boer EJ, Wilson-van den Hooven C, Etemad-Ghameslou Z, Drijvers JJMM, van Rossum CTM, *Diet of community-dwelling older adults : Dutch National Food Consumption Survey Older adults 2010-2012*. 2013.
38. Post, M., Van Asbeck, FWA., Van Dijk, AJ., Schrijvers, AJP. , *Nederlandse interviewversie van de Barthel-index onderzocht by dwarslaesiepatiënten.* Nederlands Tijdschrift voor Geneeskunde, 1995. **139**(27).
39. De Haan, R., Limburg, M., Schuling, J., Broeshart, J., Jonkers, L., Van Zuylen, P. , *Klinimetriche evaluatie van de Barthel-index, een maat voor beperkingen in het dagelijks functioneren.* Nederlands Tijdschrift voor Geneeskunde, 1993. **137**(18).
40. Guigoz, Y., *The Mini Nutritional Assessment (MNA) review of the literature--What does it tell us?* J Nutr Health Aging, 2006. **10**(6): p. 466-85; discussion 485-7.
41. Ryan, T., P. Enderby, and A.S. Rigby, *A randomized controlled trial to evaluate intensity of community-based rehabilitation provision following stroke or hip fracture in old age.* Clin Rehabil, 2006. **20**(2): p. 123-31.
42. Hsieh, Y.W., et al., *Establishing the minimal clinically important difference of the Barthel Index in stroke patients.* Neurorehabil Neural Repair, 2007. **21**(3): p. 233-8.
43. Perera, S., et al., *Meaningful change and responsiveness in common physical performance measures in older adults.* J Am Geriatr Soc, 2006. **54**(5): p. 743-9.
44. Health Council of the Netherlands, *Dietary reference intakes: energy, proteins, fats, and digestible carbohydrates*. 2001: The Hague: Health Council of the Netherlands.
45. van Til, A.J., et al., *Effects of the daily consumption of protein enriched bread and protein enriched drinking yoghurt on the total protein intake in older adults in a rehabilitation centre: a single blind randomised controlled trial.* J Nutr Health Aging, 2015. **19**(5): p. 525-30.

46. Halton, T.L. and F.B. Hu, *The effects of high protein diets on thermogenesis, satiety and weight loss: a critical review.* J Am Coll Nutr, 2004. **23**(5): p. 373-85.
47. Deutz, N.E., et al., *Protein intake and exercise for optimal muscle function with aging: recommendations from the ESPEN Expert Group.* Clin Nutr, 2014. **33**(6): p. 929-36.

Appendices

Appendix I: Cater with Care products assortment and nutritional content

Assortiment
Cater with Care studie

Cater with Care

WAGENINGEN UR
For quality of life

Ziekenhuis Gelderse Vallei

Brood

- Lichtbrood, Bruinbrood, Donkerbrood (2 sneetjes brood leveren **±5 gram eiwit extra** in vergelijking met normaal brood)
- Bruine bolletjes en rozijnenbolletjes voor de weekenden (deze bolletjes bevatten **±5 gram eiwit extra** in vergelijking met normale bolletjes)

Ontbijtpap met volkorengranen

Lekker voor het ontbijt of als tussendoortje.
Deze pap bevat **±10 gram eiwit extra**
in vergelijking met reguliere ontbijtpap.

Dranken

- Fruitsap in 3 smaken:
  appel-blauwe bes, appel-aardbei, sinaasappel
- Fruitzuivel in 3 smaken:
  bosvruchten, tropisch fruit, framboos-aardbei
- Fruitdrink met bosvruchtensmaak

Deze dranken leveren **±10 gram eiwit extra**
per portie in vergelijking met normale dranken

Soep

- Tomatensoep
- Champignonsoep
- Broccoli-bloemkoolsoep

Deze soepen leveren **±10 gram eiwit** extra per portie in vergelijking met normale soepen.

Voor de warme maaltijd

- Aardappelpuree: deze puree levert **±10 gram eiwit extra** per portie in vergelijking met normale puree.
- Kalfsvleesproducten: saucijs, gehaktbal, sukade. Deze vleesproducten zijn heerlijk mals en passen in een eiwitrijk eetpatroon.

Zuiveltoetjes

Vla en kwark zijn er in verschillende smaken verkrijgbaar, welke smaken er precies zijn, ziet u op het bestelformulier.

De toetjes bevatten **±5 gram eiwit extra** per portie in vergelijking met normale toetjes.

Tussendoortjes

- Banket: appelkoek, kersenkoek, cake met fruitvulling
- Fruit-ijs in 3 smaken: bosvruchten, abrikoos, aardbei-framboos

De banketproducten en het ijs leveren **±10 gram eiwit extra** per portie in vergelijking met vergelijkbare producten.

- Snackgehaktballetjes

Deze malse snackgehaktballetjes leveren **±20 gram eiwit per 3 stuks**. Ze zijn ook warm erg lekker als hartige snack.

Table 1. Nutritional content of the Cater with Care products.

Product	Portion size	Energy (kcal) per portion	Energy (kJ) per portion	Protein (g) per portion	Carbohydrates (g) per portion	Fat (g) per portion
Bread						
Light	36 g	96	402	5.9	12.3	2.2
Brown	34 g	85	356	6.1	9.4	2.2
Dark	33 g	82	343	5.4	9.6	1.9
Raisin bun	71 g	200	837	8.2	33.7	2.8
Brown bun	48 g	135	565	7.5	18.4	2.8
Instant breakfast porridge (30 g per sachet)	125 g	110	461	12.9	14.4	0.5
Dairy beverages						
Forest fruit	150 ml	138	578	10.1	21.0	1.5
Strawberry - raspberry	150 ml	138	578	10.1	21.0	1.5
Tropical fruit	150 ml	138	578	10.1	21.0	1.5
Dairy desserts						
Vanilla custard	150 ml	210	879	9.9	31.7	4.8
Caramel custard	150 ml	210	879	9.9	31.7	4.8
'Bitterkoekjes' custard	150 ml	210	879	9.9	31.7	4.8
Pear *quark* ('kwark')	150 ml	173	724	12.6	21.0	4.2
Strawberry *quark* ('kwark')	150 ml	173	724	12.6	21.0	4.2
Ice cream						
Forest fruit	150 ml	216	904	15.0	39.0	0.0
Raspberry-strawberry	150 ml	216	904	15.0	39.0	0.0
Fruit beverages						
Apple - strawberry	150 ml	79	331	10.1	9.6	0.0
Orange	150 ml	88	368	10.1	11.3	0.0
Apple - blueberry	150 ml	79	331	10.1	9.6	0.0
Forest fruit	200 ml	113	473	10.6	17.6	0.0
Soups						
Tomato	150 ml	98	410	10.1	6.6	3.5
Broccoli - cauliflower	150 ml	95	398	10.1	3.6	4.5
Mushroom	150 ml	96	402	10.1	3.8	4.5
Meat						
Veal meatball large	132 g	333	1399	32.7	1.3	21.9
Veal sausage	156 g	373	1567	36.9	0.8	24.6
Veal steak ('sucade')	129 g	220	925	35.5	1.3	8.1
Instant mashed potatoes (35 g per sachet)	150 g	125	523	10.5	16.5	1.5
Snacks						
Apple cake	65 g	285	1193	9.7	32.9	12.7
Cherry cake	65 g	286	1197	9.7	33.2	12.7
Raspberry cake	55 g	233	976	8.3	24.2	11.4
Veal meatballs small	25 g (per ball)	63	265	6.2	0.3	4.2

Data on the nutritional content of the CwC products are based on information provided by the manufacturers.

Appendix II: Control products assortment and nutritional content

Assortiment
Cater with Care studie

Cater with Care

WAGENINGEN UR
For quality of life

Ziekenhuis Gelderse Vallei

Brood

- Het brood is verkrijgbaar in 3 varianten: wit, bruin en volkoren.
- Bruine bolletjes en rozijnenbolletjes voor de weekenden.

Brood levert vezels en past in een gezond eetpatroon.

De volgende producten bieden wij aan ter aanvulling op uw dagelijkse eetpatroon

Gebruik deze producten als extra om meer eiwitten binnen te krijgen.

Zuiveldranken

De zuiveldrank Milk & Fruit is verkrijgbaar in twee smaken: mango en aardbei-kers.

Beide smaken bevatten per beker van 250 ml **±5 gram eiwit**.

Zuiveltoetjes

Als toetje zijn er verschillende smaken vla en yoghurt verkrijgbaar, welke smaken er precies zijn, ziet u op het bestelformulier.

Beide zijn verpakt in een-persoonsporties en bevatten **±5 gram eiwit** per portie.

Snackgehaktballetjes

Deze snackballetjes bevatten **±20 gram eiwit per 3 stuks**. Ze zijn ook warm erg lekker.

Table 2. Nutritional content of the control products.

Product	Portion size	Energy (kcal) per portion	Energy (kJ) per portion	Protein (g) per portion	Carbohydrates (g) per portion	Fat (g) per portion
Bread						
White	32 g	79	331	2.9	15.3	0.5
Brown	32 g	76	318	3.2	13.7	0.5
Whole wheat	31 g	73	306	3.4	12.1	0.7
Raisin bun	68 g	183	766	5.7	34.6	1.7
Brown bun	44 g	113	473	4.8	18.4	1.7
Dairy beverages						
Banana	250 ml	145	607	5.0	30.0	1.3
Strawberry - cherry	250 ml	158	662	5.0	31.3	1.3
Dairy desserts						
Vanilla custard	150 ml	132	553	3.3	20.3	4.2
Chocolate custard	150 ml	143	599	3.9	21.8	4.2
Fruit yoghurt	125 ml	108	452	4.4	17.5	1.9
Regular yoghurt	125 ml	64	268	5.6	5.4	1.9
Snacks						
Meatballs small	20 g (per ball)	62	261	2.8	1.2	5.1

Data on the nutritional content of the control products are based on information provided by the manufacturers.

Appendix III: Dietary food record

Datum: .....

INLEIDING VOEDSELDAGBOEKJE

Voor u ligt nu het voedseldagboekje van de Cater with Care studie. Met dit voedseldagboekje proberen we een goed inzicht te krijgen in wat u dagelijks eet en drinkt. Om daar een beeld van te krijgen vragen we u gedurende 1 dag alles wat u eet en drinkt op te schrijven in dit boekje. Het is de bedoeling dat u zo nauwkeurig mogelijk noteert welk soort **voedingsmiddel** en **hoeveel** u precies eet en drinkt. Dit is de dag waarop dit gedaan moet worden:

1. .....

Het ingevulde voedseldagboekje wordt met u doorgesproken tijdens een huisbezoek waarbij ook andere metingen gedaan worden. We nemen het dagboekje dan met u door om na te gaan of soorten producten en ingevulde hoeveelheden voor ons duidelijk zijn.

Op de volgende pagina's vindt u de richtlijnen voor het noteren van de voeding en een voorbeeld. Belangrijk is dat u de richtlijnen en voorbeelden goed doorleest, voor u begint met het invullen van het dagboekje.

Cater with Care

Datum: .....

LEES DEZE RICHTLIJNEN VOOR U BEGINT

- Houd dit dagboekje steeds bij de hand (ook als u weg gaat), zodat u meteen kunt opschrijven wat u gegeten en gedronken heeft. De kans is dan klein dat u iets vergeet te noteren.
- Schrijf alles op, ook de voedingsmiddelen die nog niet in het dagboekje staan. Denkt u ook aan alle versnaperingen tussen de maaltijden door, zoals koffie, thee (met melk en/of suiker) een snoepje, glaasje water etc.
- Het is zeer belangrijk dat u noteert hoeveel u van iets eet. Dit kunt u vermelden in huishoudelijke maten, zoals een kopje, beker, eetlepel, sneetje. De (onderdelen van de) warme maaltijd mag u ook weergeven in grammen, als dit uw voorkeur heeft.
- Omschrijf alles zo nauwkeurig mogelijk, dus bijvoorbeeld: **wit**brood; halvarine, **Becel light** (ook merknaam); **halfvolle** melk; **volvette** kaas etc.
- Voor de warme maaltijd zijn speciale bladzijden toegevoegd. Hierop kan degene die de warme maaltijd klaarmaakt noteren hoe deze is samengesteld, hoeveel ingekocht is, hoeveel gebruikt is en hoeveel personen hebben meegegeten. Dit is niet van toepassing als u de warme maaltijd van een centrale keuken krijgt.
- Als u de warme maaltijd van een centrale keuken krijgt, schrijft u op **wat** u heeft gegeten en **hoeveel** u heeft gegeten.
- U kunt gewoon blijven eten en drinken, zoals u gewend bent sinds u onze boodschappenpakketten krijgt. Wij zijn juist geïnteresseerd in wat u nu eet en drinkt.

Veel succes en alvast bedankt voor uw medewerking!

Datum: .....

IN DE LOOP VAN DE MORGEN

voedingsmiddel en soort/ merk	hoeveelheid
Dranken	
koffie	*2 bekers*
thee	
koffiemelk, soort: *halvamel*	*2x1 cupje*
suiker	
zoetstof, soort: *candarel*	*2x1 zoetje*
frisdrank, vruchtensap etc, soort:	
alcoholische dranken, soort:	
Versnaperingen	
zoet, soort: *roomboterkoekje, AH huismerk*	*1 stuks*
dropmentos	*2 stuks*
hartig, soort:	
Fruit, soort:	
Diversen	

Datum: .....

BIJZONDERHEDEN WARME MAALTIJD

alleen invullen indien u zelf de warme maaltijd bereidt

Wilt u hieronder aangeven hoe de warme maaltijd was samengesteld, dat wil zeggen de gebruikte hoeveelheden margarine, boter, olie, suiker, bloem, paneermeel, groente, aardappelen, rijst, vlees, melk, vis, kip etc. U mag de hoeveelheden van het totale recept geven of alleen de hoeveelheden van uzelf.

samenstelling en gebruikte hoeveelheden
Kerriesoep:
~ 1 kleine ui (schoongemaakt)
~ ± 10 cm van een prei
~ 1/5 deel van een pakje roomboter
~ 2 eetlepels tarwebloem
~ 1 liter bouillon van een blokje
~ 2 eetlepels koffieroom

Hoeveel heeft u zelf van dit gehele recept gegeten?

1/4 deel zelf gegeten.....

Datum: .....

ONTBIJT

HIER START HET ECHTE DAGBOEK

voedingsmiddel en soort/ merk	hoeveelheid
Brood, soort:	
knäckebröd / beschuit etc, soort:	
Smeersel, soort:	
merk:	
Broodbeleg	
kaas, soort:	
vleeswaren, soort:	
zoet beleg, soort:	
ander beleg, soort:	
Yoghurt, vla etc, soort:	
muesli, cruesli, cornflakes etc, soort:	
Pap, soort:	

Datum: .....

VERVOLG ONTBIJT

voedingsmiddel en soort/ merk	hoeveelheid
Dranken	
koffie	
thee	
koffiemelk, soort:	
suiker	
zoetstof, soort:	
melk, soort:	
overige dranken, soort:	
Fruit, soort:	
Diversen	

Datum: .....

IN DE LOOP VAN DE MORGEN

voedingsmiddel en soort/ merk	hoeveelheid
Dranken	
koffie	
thee	
koffiemelk, soort:	
suiker	
zoetstof, soort:	
frisdrank/ vruchtensap, soort:	
alcoholische dranken, soort:	
Versnaperingen	
zoet, soort:	
hartig, soort:	
Fruit, soort:	
Diversen	

Datum: .....

2e BROODMAALTIJD

voedingsmiddel en soort/ merk	hoeveelheid
Soep, soort:	
Brood, soort:	
knäckebröd / beschuit etc, soort:	
Smeersel, soort:	
merk:	
Broodbeleg	
kaas, soort:	
vleeswaren, soort:	
zoet beleg, soort:	
ander beleg, soort:	
Yoghurt, vla etc, soort:	
muesli, cruesli, cornflakes etc, soort:	
Pap, soort:	

Datum: .....

VERVOLG 2e BROODMAALTIJD

voedingsmiddel en soort/ merk	hoeveelheid
Dranken	
koffie	
thee	
koffiemelk, soort:	
suiker	
zoetstof, soort:	
melk, soort:	
overige dranken, soort:	
Fruit, soort:	
Diversen	

Datum: .....

IN DE LOOP VAN DE MIDDAG

voedingsmiddel en soort/ merk	hoeveelheid
Dranken	
koffie	
thee	
koffiemelk, soort:	
suiker	
zoetstof, soort:	
frisdrank/ vruchtensap, soort:	
alcoholische dranken, soort:	
Versnaperingen	
zoet, soort:	
hartig, soort:	
Fruit, soort:	
Diversen	

Datum: .....

WARME MAALTIJD

voedingsmiddel en soort/ merk	hoeveelheid
Soep, soort:	
Aardappelen, rijst, macaroni etc	
soort:	
bereidingswijze:	
Groente, soort:	
bereidingswijze:	
rauwkost, soort:	
dressing, slasaus, soort:	
Vlees, vis, ei, vegetarische vleesvervanger	
soort:	
bereidingswijze:	
Jus / saus, soort:	

Datum: .....

VERVOLG WARME MAALTIJD

voedingsmiddel en soort/ merk	hoeveelheid
Toevoegingen	
kaas, crème fraiche, noten etc	
soort:	
Vetsoorten voor de bereiding	
boter, margarine, olie, bak&braad etc	
soort:	
merk:	
Nagerecht, soort:	
Fruit, soort:	
Dranken, soort:	
Diversen	

Datum: .....

BIJZONDERHEDEN WARME MAALTIJD

alleen invullen indien u zelf de warme maaltijd bereidt

Wilt u hieronder aangeven hoe de warme maaltijd was samengesteld, dat wil zeggen de gebruikte hoeveelheden margarine, boter, olie, suiker, bloem, paneermeel, groente, aardappelen, rijst, vlees, melk, vis, kip etc. U mag de hoeveelheden van het totale recept geven of alleen de hoeveelheden van uzelf.

samenstelling en gebruikte hoeveelheden

Hoeveel heeft u zelf van dit gehele recept gegeten?

.....

Datum: .....

IN DE LOOP VAN DE AVOND

voedingsmiddel en soort/ merk	hoeveelheid
Dranken	
koffie	
thee	
koffiemelk, soort:	
suiker	
zoetstof, soort:	
frisdrank/ vruchtensap, soort:	
alcoholische dranken, soort:	
Versnaperingen	
zoet, soort:	
hartig, soort:	
Fruit, soort:	
Diversen	

Appendix IV: Barthel Index questionnaire

Deelnemer-nummer:

Cater with Care

ADL-vragenlijst over Activiteiten in het Dagelijks Leven

			Score	
1. Bent u in staat zelfstandig uw gezicht, tanden en haar te verzorgen	Nee, daarbij heb ik hulp nodig.		0	
	Ja, dat kan ik zelfstandig.		1	
2. Bent u in staat om zelfstandig het toilet te gebruiken?	Nee, daarbij heb ik hulp nodig.		0	
	Soms heb ik hulp nodig.		1	
	Ja, dat kan ik zelfstandig.		2	
3. Heeft u last gehad van incontinentie voor urine?	Ja, ik ben incontinent.		0	
	Soms ben ik incontinent.		1	
	Nee.		2	
4. Heeft u last gehad van incontinentie voor ontlasting?	Ja, ik ben incontinent.		0	
	Soms ben ik incontinent.		1	
	Nee.		2	
5. Heeft u hulp nodig bij het eten bereiden?	Ja, daarbij heb ik hulp nodig.		0	
	Ik heb alleen hulp nodig bij snijden en smeren.		1	
	Nee, dat kan ik zelfstandig.		2	
6. Kunt u zelfstandig van uw bed naar uw stoel lopen?	Nee.		0	
	Daar heb ik veel hulp bij nodig.		1	
	Daar heb ik weinig hulp bij nodig.		2	
	Ja, dat kan ik zelfstandig.		3	
7. Heeft u hulp nodig bij het verplaatsen in huis?	Ik kan me niet zelfstandig verplaatsen.		0	
	Ik kan me verplaatsen in een rolstoel.		1	
	Ik kan lopen met hulp van een ander.		2	
	Ik kan zelfstandig lopen, eventueel met een rollator of stok.		3	
8. Kunt u zich zelfstandig aan- en uitkleden?	Nee, daarbij heb ik hulp nodig.		0	
	Ongeveer de helft kan ik zelf.		1	
	Ja, dat kan ik zelfstandig.		2	
9. Kunt u zelfstandig traplopen?	Nee, helemaal niet.		0	
	Nee, daar heb ik hulp bij nodig.		1	
	Ja, ik kan zelfstandig de trap op en af.		2	
10.Heeft u hulp nodig bij het in bad gaan of douchen?	Ja, daarbij heb ik hulp nodig.		0	
	Nee, dat kan ik zelfstandig.		1	
		Totaal		

Appendix V: Instructions and scoring criteria Short Physical Performance Battery

Short Physical Performance Battery (SPPB)

1. BALANSTEST

De deelnemer moet in staat zijn te staan zonder hulp van stok of rollator. Het is toegestaan de deelnemer te helpen met opstaan.

We gaan nu beginnen met de oefeningen. Ik zou graag willen dat u een aantal oefeningen probeert uit te voeren. ***Ik zal de oefening steeds eerst voordoen.*** *Vervolgens wil ik graag dat u het probeert. Als u niet in staat bent de oefening uit te voeren, of denkt dat het niet veilig is de oefening uit te voeren, maak dit dan kenbaar, dan gaan we door naar de volgende oefening. Ik wil niet dat u een oefening doet waarvan u een onveilig gevoel krijgt. Bij de oefeningen staan mijn collega en ik bij u voor de veiligheid.*

Hebt u nog vragen voordat we beginnen?

A. VOETEN TEGEN ELKAAR POSITIE

1. *Ik zal u nu de eerste positie laten zien (DEMONSTRATIE).*
2. *Ik wil graag dat u probeert met uw voeten tegen elkaar te staan voor ongeveer 10 seconden.*
3. *U mag uw armen gebruiken, uw knieën buigen, of uw lichaam bewegen om in balans te blijven zolang uw voeten maar op één plek blijven staan. Probeer de deze positie vast te houden totdat ik zeg dat u mag stoppen.*
4. Ga naast de deelnemer staan en help hem/haar met de voeten tegen elkaar positie.
5. Lever net genoeg steun aan de arm van de deelnemer om te voorkomen dat deze het evenwicht verliest.
6. Als de deelnemer de voeten bij elkaar heeft, vraag dan: *Bent u klaar?*
7. Laat dan los en begin met de tijdsmeting terwijl je zegt: *Klaar, begin.*
8. Stop de stopwatch en zeg *stop* na 10 seconden, of als de deelnemer uit positie komt of je arm pakt.
9. Als de deelnemer niet in staat is deze positie 10 seconden vol te houden, schrijf het resultaat dan op, en ga dan door naar de **looptest.**

B. SEMI-TANDEM POSITIE

1. *Ik zal u nu de tweede positie laten zien (DEMONSTRATIE).*
2. *Ik wil graag dat u probeert te staan met de ene voet voor de ander, zodat de zijkant van de hiel van uw ene voet de grote teen van de ander raakt, voor ongeveer 10 seconden. U mag zelf bepalen welke voet u voorop zet, wat voor u het meest comfortabel is.*
3. *U mag uw armen gebruiken, uw knieën buigen, of uw lichaam bewegen om in balans te blijven zolang uw voeten maar op een plek blijven staan. Probeer deze positie vast te houden totdat ik zeg dat u mag stoppen.*
4. Ga naast de deelnemer staan en help hem/haar met de semi-tandem positie.
5. Lever net genoeg steun aan de arm van de deelnemer om te voorkomen dat deze het evenwicht verliest.
6. Als de deelnemer de voeten in de juiste positie heeft, vraag dan: *Bent u klaar?*
7. Laat dan los en begin met de tijdsmeting terwijl je zegt: *Klaar, begin.*
8. Stop de stopwatch en zeg *stop* na 10 seconden, of als de deelnemer uit positie komt of je arm pakt.
9. Als de deelnemer niet in staat is deze positie 10 seconden vol te houden, schrijf het resultaat dan op, en ga dan door naar de **looptest.**

C. TANDEM POSITIE

1. *Ik zal u nu de derde positie laten zien (DEMONSTRATIE).*
2. *Ik wil graag dat u probeert te staan met de ene voet voor de andere, zodat de hiel van uw ene voet de teen van de ander raakt, voor ongeveer 10 seconden. U mag zelf bepalen welke voet u voorop zet, wat voor u het meest comfortabel is.*
3. *U mag uw armen gebruiken, uw knieën buigen, of uw lichaam bewegen om in balans te blijven zolang uw voeten maar op een plek blijven staan. Probeer de deze positie vast te houden totdat ik zeg dat u mag stoppen.*
4. Ga naast de deelnemer staan en help hem/haar met de tandem positie.
5. Lever net genoeg steun aan de arm van de deelnemer om te voorkomen dat deze het evenwicht verliest.
6. Als de deelnemer de voeten in de juiste positie heeft, vraag dan: *Bent u klaar?*

7. Laat dan los en begin met de tijdsmeting terwijl je zegt: *Klaar, begin.*

8. Stop de stopwatch en zeg *stop* na 10 seconden, of als de deelnemer uit positie komt of je arm pakt.

9. Schrijf het resultaat op.

---

2. <u>LOOPTEST (4 meter)</u>

Nu gaan we kijken hoe u normaal loopt. Als u een stok of ander loophulpmiddel gebruikt en u hier comfortabeler mee voelt, dan mag u deze gebruiken.

A. EERSTE KEER LOOPTEST

1. *Dit is ons loopparcours. Ik wil dat u helemaal tot de ander kant van het parcours loopt met uw gebruikelijke loopsnelheid, alsof u over straat loopt naar de winkel. Loop door totdat u helemaal voorbij de streep bent. Ik zal met u meelopen. Hebt u het gevoel dat dit veilig is?*

2. Demonstreer het lopen voor de deelnemer.

3. Als u moet beginnen zal ik zeggen: *Klaar, start.*

4. Laat de deelnemer zo staan dan beide voeten de startlijn raken.

5. ALS DE DEELNEMER IN POSITIE STAAT VOOR DE STARTLIJN, ZEG DAN: *Klaar, start.*

6. Druk op de startknop van de stopwatch als de deelnemer begint te lopen.

7. Loop achter en naast de deelnemer.

8. Stop de tijdmeting als één voet helemaal over de eindstreep komt.

B. TWEEDE KEER LOOPTEST

Nu wil ik graag dat u deze looptest nog een keer doet. Onthoud om uw gebruikelijke loopsnelheid aan te houden, en loop helemaal door tot het einde van het parcours.

---

3. STOEL TEST



A. Denkt u dat het veilig is om op te staan uit een stoel zonder uw handen te gebruiken?

B. De volgende oefening meet de kracht in uw benen.

C. (Demonstreer en leg de procedure uit): Vouw eerst uw armen voor uw borst en zit zodat uw beide voeten op de vloer staan; sta dan op en hou uw handen voor uw borst gevouwen. (Noteer resultaat)

D. Als de deelnemer niet kan opstaan zonder het gebruik van hun armen, laat ze het dan proberen **met** gebruik van hun armen. (Noteer resultaat)

HERHAALDE STOEL TEST

A. Denkt u dat het veilig is om vijf keer op te staan uit een stoel zonder uw handen te gebruiken?

B. (Demonstreer en leg de procedure uit): Ga vijf keer rechtop staan zo **SNEL** mogelijk, zonder tussendoor te stoppen. Elke keer na het opstaan weer gaan zitten. Houd uw handen voor uw borst gevouwen. Ik zal uw tijd opnemen met een stopwatch.

C. Als de deelnemer correct zit, zeg: *Klaar? Start*, en begin de meting.

D. Tel hardop mee elke keer als de deelnemer rechtop komt, tot vijf.

E. Stop als de deelnemer moe wordt of kortademig.

F. Stop de stopwatch als de deelnemer voor de vijfde keer rechtop staat.

G. Stop ook als:
   1. De deelnemer zijn/haar handen gebruikt.
   2. Na 1 minuut de deelnemer niet staat.
   3. U bezorgd bent over de veiligheid van de deelnemer.

H. ALS DE DEELNEMER STOPT EN ER MOE UITZIET VOORDAT DE OEFENING VOLTOOID IS, BEVESTIG DIT DOOR TE VRAGEN: *Kunt u doorgaan?*

I. Als de deelnemer *'Ja'* antwoordt, ga dan door met de tijdmeting. Als de deelnemer *'Nee'* antwoordt, stop en reset de stopwatch.

Deelnemer-nummer: ……..

Datum: ……..

Testafnemer: ……..

SCOREFORMULIER Short Physical Performance Battery (SPPB)

1. BALANSTEST

A. VOETEN TEGEN ELKAAR POSITIE

10 seconden volhouden ___ **1 punt**
Niet 10 seconden volgehouden ___ **0 punten**
Niet geprobeerd ___ **0 punten**
Indien 0 punten, stop de Balanstest

Aantal seconden volgehouden indien onder de 10 seconden: …….. seconden

Indien niet geprobeerd/voltooid, kruis reden aan:
Geprobeerd, maar niet in staat ___
Deelnemer kon niet zonder hulp opstaan ___
Niet geprobeerd, onveilig gevoel ___
Deelnemer begreep de instructies niet ___
Deelnemer weigerde ___
Anders: _____

B. SEMI-TANDEM POSITIE

10 seconden volhouden ___ **1 punt**
Niet 10 seconden volgehouden ___ **0 punten**
Niet geprobeerd ___ **0 punten**
Indien 0 punten, stop de Balanstest

Aantal seconden volgehouden indien onder de 10 seconden: …. seconden

C. TANDEM POSITIE

10 seconden volhouden ___ **2 punt**
3 tot 9 seconden volgehouden ___ **1 punten**
< 3 seconden volgehouden ___ **0 punten**
Niet geprobeerd ___ **0 punten**

Aantal seconden volgehouden indien onder de 10 seconden: …. seconden

D. TOTALE SCORE BALANS OEFENINGEN: …… (optellen)

Opmerkingen:

_____

_____

Deelnemer-nummer: ……..……..
Datum: ……..
Testafnemer: ……..

---

2. LOOPTEST

Lengte van het loopparcours: Vier meter ___
Drie meter ___

A. Duur eerste looptest (in seconden)

1. Tijd voor 4 meter parcours ……. seconden
2. Als het parcours **niet** voltooid/begonnen is: Geweigerd___ Niet in staat___ Onveilig gevoel___
   (GA DOOR MET DE STOEL TEST)
3. Hulpmiddelen bij eerste loop: Geen___ Stok___ Anders___

Opmerkingen:_____

B. Duur tweede looptest (in seconde)

1. Tijd voor 4 meter parcours ……. seconden
2. Als het parcours **niet** voltooid/begonnen is: Geweigerd___ Niet in staat___ Onveilig gevoel___
   (GA DOOR MET DE STOELTEST)
3. Hulpmiddelen bij eerste loop: Geen___ Stok___ Anders___

SNELSTE TIJD VAN DE TWEE LOOPTESTEN

Snelste tijd: ……. seconden [als er maar 1 looptest is uitgevoerd, dan deze tijd]

Als de deelnemer **niet in staat** was de looptest uit te voeren: ___ **0 punten**

4 meter looptest:

Tijd langer dan 8.70 seconden: ___ **1 punt**
Tijd van 6.21 tot 8.70 seconden ___ **2 punten**
Tijd van 4.82 tot 6.20 seconden ___ **3 punten**
Tijd korter dan 4.82 seconden: ___ **4 punten**

Deelnemer-nummer: ……..……..…..
Datum: ……..
Testafnemer: ……..

---

3. STOELTEST	**Ja**	**Nee**
A. Veilig bevonden om op te staan zonder hulp:	___	___
B. Resultaat:		
Deelnemer stond op zonder gebruik van armen:	___	___
Deelnemer gebruikte zijn/haar armen:	___	___
Test niet voltooid	___	___

C. INDIEN NIET VOLTOOID/ OF NIET BEPROBEERD

Niet in staat op te staan ___

Deelnemer weigerde ___

HERHAALDE STOEL TEST	**Ja**	**Nee**
A. Veilig bevonden om vijf keer op te staan zonder hulp:	___	___

B. INDIEN DE VIJF HERHALINGEN SUCESVOL VOLTOOID ZIJN, IN HOEVEEL SECONDEN:

Tijd om vijf herhalingen te voltooien: ……seconden.

C. INDIEN NIET VOLTOOID/ OF NIET BEPROBEERD

Niet in staat om vijf herhalingen te voltooien	___	___
Deelnemer begreep de instructies niet	___	___
Deelnemer weigerde	___	___

Niet in staat om de oefening te voltooien: ___ **0 punten**
Tijd langer dan 16.6 seconden: ___ **1 punt**
Tijd van 13.7 tot 16.6 seconden ___ **2 punten**
Tijd van 11.2 tot 13.6 seconden ___ **3 punten**
Tijd korter dan 11.2 seconden: ___ **4 punten**

Deelnemer-nummer: ……..
Datum: ……..

Testafnemer: ……..

TOTALE SPPB TEST SCORE

Balanstest score: …….

Looptest score: …….

Stoeltest score: …….

_____+

TOTALE SCORE …….

Appendix VI: Previous studies reporting mean daily protein intake levels of older adults admitted to the hospital or recently discharged from the hospital

Table 3. Studies reporting on mean daily protein intake levels of elderly patients admitted to the hospital or recently discharged from the hospital.

Author, year.	Title	Description	Results on protein intake (mean ± SD)
Van Geel, J. (un-published data)	Protein and energy intake in hospitalized elderly	Master thesis involving an observational study assessing the dietary intake of 80 older adults admitted to hospital Gelderse Vallei.	Actual protein intake at fourth day of admission Whole study population (N=63): **0,93 ± 0,41 g/kg BW/day** Patients with low risk of malnutrition (MUST 0) (N=76): **0,80 ± 0,31 g/kg BW/day** Patients with medium or high risk of malnutrition (MUST≥1) (N=78) **1,03 ± 0,46 g/kg BW/day**
Stelten, S. 2014 [10]	Protein-enriched 'regular products' and their effect on protein intake in acute hospitalized older adults; a randomized controlled trial	RCT in 47 hospitalized Dutch elderly patients, assessing the effect of protein-enriched bread and drinking yoghurt compared to regular bread and drinking yoghurt on protein intake.	Mean protein intake after three consecutive intervention days: Control group (N= 25): **0,9±0,3 g/kg BW/day**
Neelemaat, F. 2012 [17]	Post-discharge nutritional support in malnourished elderly individuals improves functional limitations	RCT trial in 210 hospitalized Dutch elderly patients (≥60 years), assessing the effect of standard protein-energy enriched diet + ONS + nutritional counselling compared to usual care on functional limitations in three months after discharge.	Protein intake at baseline (within 3 days following hospital admission) Control group (N=105): **0,9±0,6 g/kg BW/day** Protein intake after 3 months following hospital discharge Control group (N=75): **1,0±0,5 g/kg BW/day**

Appendix VII: Tests for normality

Table 4: P-values of Shapiro-Wilk test for normal distribution mean body weight unadjusted (kg), mean body weight adjusted (kg) and BMI (kg/m2).

	Week 2[a]		Week 6[b]		Week 12[c]	
	Control	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
Body weight (kg)	0,017	0,149	0,003	0,140	0,011	0,129
Adjusted body weight (kg)	0,952	0,724	0,772	0,557	0,433	0,709
BMI (kg/m^2)	0,034	0,003	0,005	0,001	0,038	<0,001
MNA total score	0,326	0,535	0,145	0,905	0,125	0,678

[a] Control: (N=21) and Intervention: (N=20).
[b] Control: (N=21) and Intervention: (N=21).
[c] Control: (N=20) and Intervention: (N=20).

Table 5: P values pf Shapiro-Wilk test for normal distribution of protein intake levels.

	Control	Intervention
Protein intake (g/day)		
Week 2[a]	0,274	0,625
Week 6[b]	0,817	0,135
Week 12[c]	0,421	0,185
Protein intake (g/kg BW/day)		
Week 2[a]	0,685	0,045
Week 6[b]	0,359	0,024
Week 12[c]	0,367	0,023

[a] Week 2: Control (N=21) and Intervention (N=20).
[b] Week 6: Control (N=21) and Intervention (N=21).
[c] Week 12: Control (N=19) and Intervention (N=19).

Table 6: P values of Shapiro-Wilk test for normal distribution of energy intake levels.

	Control	Intervention
Energy intake (kcal/day)		
Week 2[a]	0,548	0,140
Week 6[b]	0,136	0,127
Week 12[c]	0,120	0,182
Energy derived from protein (En%)		
Week 2[a]	0,583	0,512
Week 6[b]	0,887	0,982
Week 12[c]	0,175	0,195

[a] Week 2: Control (N=21) and Intervention (N=20).
[b] Week 6: Control (N=21) and Intervention (N=21).
[c] Week 12: Control (N=19) and Intervention (N=19).

Table 7: P-values of Shapiro-Wilk test for normal distribution of Barthel index score.

	Control	Intervention
Week 2	0,030	0,001
Week 6	0,005	<0,001
Week 12	0,017	0,010

[a] **Week 2: Control (N=21) and Intervention (N=20).**
[b] **Week 6: Control (N=21) and Intervention (N=21).**
[c] **Week 12: Control (N=20) and Intervention (N=19).**

Table 8: P-values of Shapiro-Wilk test for normal distribution of changes in Barthel index scores.

	Control	Intervention
Week 2 - Week 6	0,002	<0,001
Week 2 - Week 12	0,024	0,133
Week 6 - Week 12	<0,001	0,036

Table 9: P-values of Shapiro-Wilk test for normal distribution of SPPB score.

	Control	Intervention
SPPB total score		
Week 2[a]	0,597	0,006
Week 6[b]	0,087	0,009
Week 12[c]	0,010	0,014

[a] **Control (N=20), Intervention (N=20).**
[b] **Control (N=20), Intervention (N=21).**
[c] **Control (N=19), Intervention (N=20).**

Table 10: P-values of Shapiro-Wilk test for normal distribution of changes in SPPB total scores.

	Control	Intervention
Week 2 - Week 6	0,019	0,092
Week 2 - Week 12	0,061	0,021
Week 6 - Week 12	0,055	0,095

Appendix VIII: Body weight, BMI and MNA score of study population at week 2, 6 and 12

Table 11. Body weight, BMI and MNA score of the study population at week 2, 6 and 12.

	Control	Intervention
Body weight (kg), median [IQR]		
Week 2	76,6 [66,3 – 84,2]	70,7 [64,3 – 85,7]
Week 6	75,6 [66,9 – 84,9]	72,5 [65,9 – 84,2]
Week 12	73,9 [68,0 – 83,9]	74,4 [65,7 – 83,9]
Body weight (kg), mean ± SD		
Week 2	77,4 ± 18,1	74,4 ± 14,6
Week 6	77,7 ± 17,9	74,7 ± 13,9
Week 12	76,8 ± 18,3	74,7 ± 14,9
Adjusted weight (kg)[a], mean ± SD		
Week 2	70,8 ± 9,5	69,1 ± 8,9
Week 6	71,7 ± 9,7	69,7 ± 8,4
Week 12	71,1 ± 10,6	69,2 ± 9,4
BMI (kg/m^2), median [IQR]		
Week 2	27,1 [23,9 – 30,4]	26,4 [23,5 – 28,6]
Week 6	27,9 [24,1 – 29,9]	26,3 [23,8 – 28,1]
Week 12	27,6 [24,2 – 29,3]	26,2 [23,9 – 28,2]
MNA total score[b], mean ± SD		
Week 2	24,4 ± 2,5	24,0 ± 2,9
Week 6	25,7 ± 2,2	24,1 ± 2,9
Week 12	25,4 ± 2,7	24,9 ± 2,8

Week 2: Control: (N=21) and Intervention: (N=20).
Week 6: Control: (N=21) and Intervention: (N=21).
Week 12: Control: (N=20) and Intervention: (N=20).
[a] Body weight adjusted to ideal body weight (IBW) for participants with a BMI > 27 kg/m^2 or BMI < 20 kg/m^2.
[b] Mini Nutritional Assessment [40].

Appendix IX: Proportion of participants achieving the recommended protein intake levels

Table 12. Number of participants achieving the recommended dietary allowance (RDA) of 0,8 g/kg BW/day.

	Protein requirement 0,8 g/kg BW/day		
	Control	**Intervention**	**P-value**
Week 2[a]	18 (86%)	20 (100%)	0,232
Week 6[b]	17 (81%)	20 (95%)	0,343
Week 12[c]	17 (90%)	18 (95%)	0,604

Data are displayed as n (%) and were analysed with Fisher's exact test.
[a] **Control: (N=21) and Intervention: (N= 20).**
[b] **Control: (N=21) and Intervention: (N=21).**
[c] **Control: (N=19) and Intervention: (N=19).**

Table 13. Number of participants achieving the recommended protein intake levels of 1,2 – 1,5 g/kg BW/day.

	Protein requirement 1,2 g/kg BW/day			Protein requirement 1,5 g/kg BW/day		
	Control	**Intervention**	**P-value**	**Control**	**Intervention**	**P-value**
Week 2[a]	11 (52%)	18 (90%)	0,008	3 (14%)	13 (65%)	0,001
Week 6[b]	8 (38%)	17 (81%)	0,005	3 (14%)	15 (71%)	<0,001
Week 12[c]	8 (42%)	14 (74%)	0,049	3 (16%)	10 (53%)	0,017

Data are displayed as n (%) and were analysed with Chi-square test.
[a] **Control: (N=21) and Intervention: (N=20).**
[b] **Control: (N=21) and Intervention: (N=21).**
[c] **Control: (N=19) and Intervention: (N=19).**

Appendix X: Relative contribution of different food groups to total protein intake

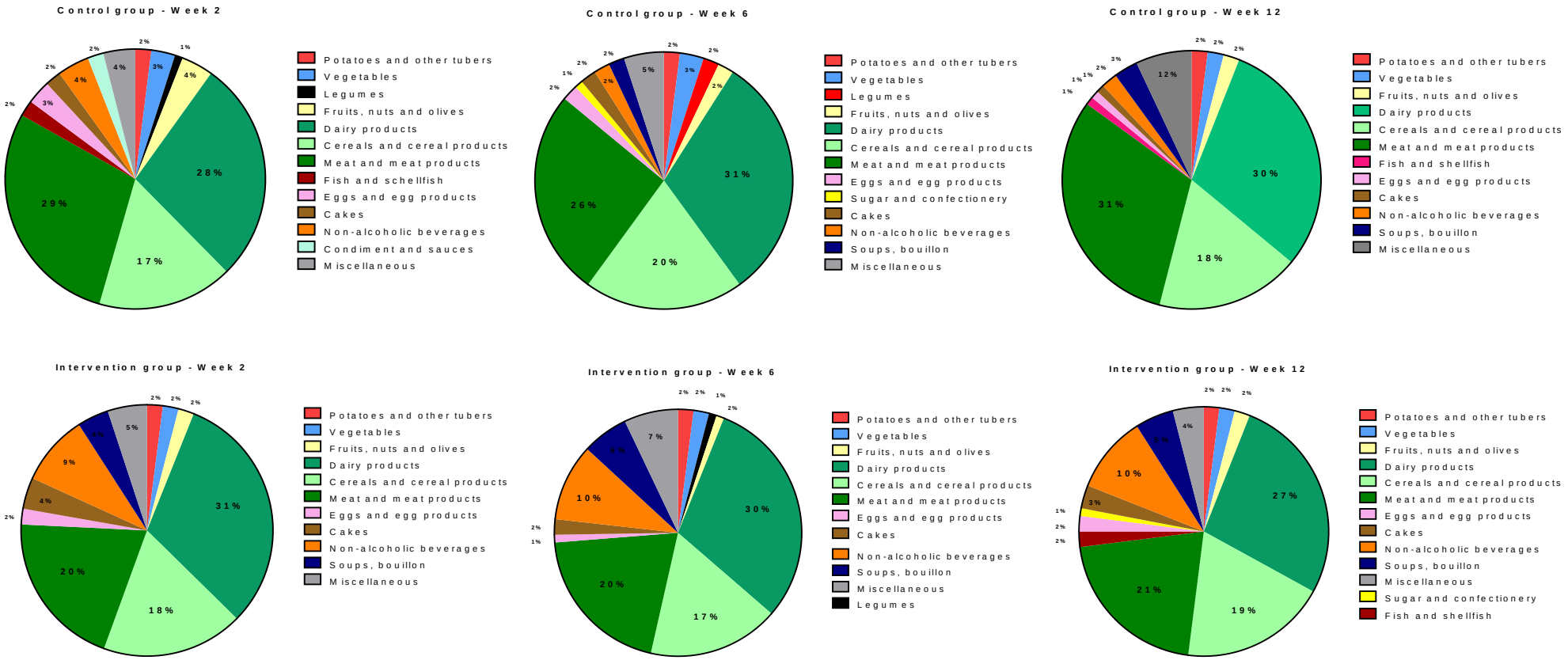

Figure 1: Relative contribution of different food groups to the total protein intake of both groups at week 2, 6 and 12. Consumed products were classified into 17 different food groups corresponding to the EPIC-soft classification as used in the Dutch National Food Consumption Survey (VCP) older adults 2010-2012 [37].

Appendix XI: Daily protein and energy intake after excluding participants using ONS

Table 14. Daily protein intake of both groups in grams per kilogram body weight per day (g/kg BW/day) at week 2, 6 and 12 after exclusion of participants using oral nutritional supplements (ONS).

	Control	Intervention	Mean difference ± SE Difference	P-value
Week 2[a]	78,8 ± 20,2	120,6 ± 33,3	41,8 ± 9,1	<0,001*
Week 6[b]	77,4 ± 21,0	121,2 ± 49,8	43,7 ± 11,8	0,001*
Week 12[c]	81,1 ± 20,3	110,1 ± 41,0	28,9 ± 11,1	0,014*

Data are presented as mean ± SD and were analysed with Independent samples T-test.
*** p< 0,05 indicates significance.**
[a] Control (N=19) and Intervention (N=18).
[b] Control (N=19) and Intervention (N=19).
[c] Control (N=17) and Intervention (N=17).

Table 15. Daily energy intake (kcal/day) at week 2, 6 and 12 after exclusion of participant using oral nutritional supplements (ONS).

	Control	Intervention	Mean difference ± SE Difference	P-value
Energy intake (kcal/day)				
Week 2[a]	1197 ± 497	2299 ± 585	301 ± 178	0,100
Week 6[b]	1956 ± 471	2152 ± 790	196 ± 203	0,393
Week 12[c]	1959 ± 593	2194 ± 561	235 ± 198	0,244

Data are presented as mean ± standard deviation and were analysed with independent samples T-test.
[a] Control (N=19) and Intervention (N=18).
[b] Control (N=19) and Intervention (N=19).
[c] Control (N=17) and Intervention (N=17).

Appendix XII: Change in BI score and SPPB score between different time points in both groups

Table 16. Change in Barthel index score between different time points.

	Control		Intervention		P-value
	Median [IQR]	**Mean ± SD**	**Median [IQR]**	**Mean ± SD**	
Week 2 – Week 6	0,0 [-1,8 – 0,0]	-0,6 ± 1,2	0,0 [0,0 – 1,0]	0,7 ± 2,0	0,028
Week 2 – Week 12	-1,0 [-2,0 – 0,0]	-1,2 ± 1,5	0,0 [-1,0 – 1,0]	0,5 ± 1,8	0,040
Week 6 – Week 12	-1,0 [-1,0 – 0,0]	-0,5 ± 1,6	0,0 [-0,8 – 0,0]	-0,2 ± 1,0	1,000

Data are presented as median [IQR] and were analysed with Mann-Whitney U test.
P< 0,017 indicates significance.

Table 17. Change in SPPB total score of both groups.

	Control		Intervention		P-value
	Median [IQR]	**Mean ± SD**	**Median [IQR]**	**Mean ± SD**	
Week 2 – Week 6	0,0 [0,0 – 1,0]	0,3 ± 0,9	0,0 [-1,0 – 1,0]	0,1 ± 1,1	0,540
Week 2 – Week 12	0,0 [-0,2 – 2,0]	0,3 ± 1,4	0,0 [0,0 – 1,0]	0,3 ± 1,0	0,784
Week 6 – Week 12	0,0 [-1,0 – 1,0]	0,0 ± 1,5	0,0 [0,0 – 1,0]	0,1 ± 1,4	0,957

Data are presented as median [IQR] and mean ± SD. Analyses were performed with Mann-Whitney U test.