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Randomized Controlled Trial

HOMEFOOD randomised trial – Six-month nutrition therapy improves quality of life, self-rated health, cognitive function, and depression in older adults after hospital discharge

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SUMMARY

Background and aims: Malnutrition is common among older adults and is related to quality of life, cognitive function, and depression. To what extent nutrition interventions can improve these outcomes remains unclear. The aim of this study was to investigate the effect of nutrition therapy on health-related quality of life (EQ-5D), self-rated health, cognitive function, and depression in community dwelling older adults recently discharged from hospital.

Methods: Participants (>65 years) were randomised into an intervention (n = 53) and a control group (n = 53). The intervention group received individualised nutrition therapy based on the nutrition care process including 5 home visits and 3 phone calls, in combination with freely delivered energy- and protein-rich foods and oral nutrition supplements for six months after hospital discharge. EQ-5D, self-rated health, Mini-Mental-State-Examination (MMSE), and the Centre for Epidemiologic Studies Depression – IOWA (CES-D) scale were measured at baseline and at endpoint.

Results: Two subjects dropped out, one from each arm. The control group experienced an increase in depressive symptoms and a decrease in self-rated health during the study period, while the intervention group experienced increases in cognitive function, self-rated health, and EQ-5D resulting in significant endpoint differences between the groups: EQ-5D (0.102, P = 0.001); self-rated health: 15.876 (P < 0.001); MMSE: 1.701 (P < 0.001); depressive symptoms: - 3.072 (P < 0.001); all in favour of the intervention group. Improvements during the intervention in MMSE, self-rated health, and CES-D were significantly related to body weight gain in a linear way.

Conclusion: Cognitive function and mental well-being worsen or stagnate in older adults who receive standard care after hospital discharge. However, a six-month nutrition therapy improves these outcomes leading to statistically and clinically significant endpoint differences between the groups. As improvements were related to body weight gain after hospital discharge, we conclude that the increase in dietary intake, with focus on energy and protein density, and changes in body weight might have contributed to better cognitive function and mental well-being in older adults after the intervention.

Abbreviations:: BMI, Body Mass Index; CES-D, Centre for Epidemiologic Studies – Depression; CI, Confidence Interval; CONSORT, Consolidated Standards of Reporting Trials; EQ-5D, Health-related Quality of Life; Kcal/day, kilocalories per day; Kg, Kilogram; MMSE, Mini Mental State Examination; SD, Standard Deviation; SPSS, Statistical Package for the Social Sciences; SRH, Self-Rated Health; VAS, Visual Analogue Scale.

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1. Introduction

Malnutrition is a frequently observed condition in vulnerable older adults [1] and this condition strongly predicts poor physical outcomes, e.g., low muscle strength [2], decreased function [3], and increased dependence [4]. However, several observational studies have also found relationships between poor nutrition status and measurements of mental well-being and cognitive function [5–13] which represent important constituents of successful ageing [14].

Depression is a frequent psychological condition observed in older adults [5] and those suffering from malnutrition are more likely to be diagnosed with such a condition. Depression at an older age is also associated with poor food intake, weight loss, and a higher risk of becoming malnourished [5,6].

Poor nutrition has also been associated with poor cognitive function; older adults with dementia have frequently been found to be underweight [7,8], which is commonly explained by weight loss prior to or during the onset or process of the disease, as evidenced by several studies [7,9,10].

Self-rated health is an important instrument in ageing research as it predicts future institutionalisation [15,16], hospitalisation [17], morbidity [18], and mortality [19]. Poor self-rated health has been frequently reported in older adults in various research settings and has been associated with low food intake or poor nutrition [11,12].

In many countries, quality of life in older adults is routinely assessed by standard questionnaires and has developed into a key outcome in gerontological research [13,20]. Health related quality of life is an aspect of this wider concept focusing on mental, physical, and social functioning [13,20]. As appropriate nutrition forms a cornerstone of good health [21], it is not surprising that results from a systematic review reported that older adults with malnutrition more often experience a low quality of life [12].

As many of the above-mentioned studies on malnutrition and mental well-being are observational in nature [5–13], they do not provide information on the direction of the observed associations and whether an improvement in nutrition status would lead to actual improvements in quality of life, self-rated health, cognitive function, or depression. There is good evidence available from clinical trials suggesting that a corrected nutrition status can increase quality of life for hospital patients and nursing home residents, but only one study is available for discharged community dwelling older adults [22].

Dietary intervention studies on the effects of nutrition intervention on self-rated health, depression, or cognitive function in older adults are either very few [23] and/or report unclear results [24,25].

To gain more knowledge on nutrition and mental well-being, we conducted this secondary analysis of a randomised dietary intervention trial. The aim of the present study was to investigate the effects of a six-month nutrition therapy on quality of life, self-rated health, cognitive function, and depression in older adults discharged from hospital.

2. Materials and methods

2.1. Study design

The HOMEFOOD study was a six-month, randomised controlled, assessor blinded intervention trial investigating the effects of nutrition therapy on older adults at nutritional risk discharged from hospital. The primary outcomes of the original study were body weight and physical function. The main outcomes of this secondary analysis of the trial were quality of life, self-rated health, cognitive function, and depressive symptoms. The study was conducted in Reykjavik, Iceland, with the first participant recruited and receiving intervention in January 2019 and the last participant recruited in January 2020 and receiving the last intervention in July 2020.

2.2. Reporting, approval, and funding

This study was conducted and is being reported following the Consolidated Standards of Reporting Trials (CONSORT) guidelines for Randomized Trials of Nonpharmacologic Treatments [26]. The study was approved by the Ethics Committee for Health Research of the National University Hospital of Iceland and data protection registry (24/2018) in August 2018 and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki [27]. This study was registered and is available at clinicaltrials.gov (NCT03995303).

2.3. Recruitment

Participants were screened and recruited by a clinical nutritionist at the Icelandic National Hospital in Reykjavik, Iceland, in collaboration with nurses from September 2018 to January 2020. Eligible participants were community dwelling patients discharging home from the hospital within 24 h, aged ≥65 years, and at risk for malnutrition according to the validated Icelandic Nutrition Screening Tool [28]. Eligible participants also had to live in the Reykjavik Capital Area, not be receiving tubal feeding, and have a cognitive function ≥20 according to the Mini Mental State Examination (MMSE) assessed within the last three months [29]. Subjects who were in active cancer treatment or with heart failure at higher stages were not included in the study. All recruited participants delivered a written informed consent.

2.4. Randomisation

The participants were randomly allocated (allocation ratio = 1:1) to either the intervention or the control group by using a random number generated by the principal investigator (AR) using Statistical Package for the Social Sciences (SPSS, version 26.0, SPSS, Chicago, IL, USA). The allocation sequence was concealed from the clinical nutritionist (BSB) who enrolled and assigned the participants to the two groups until the moment of assignment.

2.5. Intervention

Participants assigned to the intervention group received nutrition therapy from a clinical nutritionist consisting of five home visits (one day after hospital discharge; as well as one, three, six, and twelve weeks later). In addition, three individual telephone calls were made at two, five, and nine weeks after hospital discharge. The nutrition therapy was designed according to the principles of the Nutrition Care Process which includes nutritional assessment, diagnosis, intervention, monitoring, and evaluation of the therapy [30]. During the dietary counselling sessions, family members, relatives, friends, or home-care workers were invited to join in. At the initial visit, the participant was educated about the importance of adequate energy and protein intake and received the Icelandic nutrition guidelines for frail or sick older adults [31]. Nutrition related problems were identified, and suggestions were given to resolve them. In addition to the dietary advice, participants received free supplemental energy- and protein-rich foods (one hot meal/day and two in-between-meals/day; Appendix 1) delivered once a week for 24 weeks. During the first home delivery, study staff educated the participants on how to store the meals, how to open the packages, and how to heat the meals.

2.6. Control group

At discharge, the control group received standard care which consists of a booklet on good nutrition during ageing, published by the Icelandic Directorate of Health [31]. They were also recommended to order home delivered food (Meals on Wheels) upon discharge as they were at nutritional risk. No further dietary counselling during the study period was implemented which reflects the current standard of care in Iceland for older adults discharged home from the hospital.

2.7. Baseline and endpoint assessment

Measurements were conducted at baseline (at the hospital) and at endpoint (at the participants' homes). Outcome measurements were conducted in a predefined order and questions on food or diet were asked only at the very end of the endpoint home assessment. As the outcome assessors (who did not deliver the intervention) were unaware whether a participant was in the control or intervention group, measurements of EQ-5D, self-rated health, MMSE, and the CES-D scale were blinded.

Socio demographic characteristics including age, sex, social status, education, living arrangements, alcohol use, and smoking habits were assessed using questionnaires.

Health related quality of life and self-rated health were assessed using the EuroQol Group's EQ-5D instrument (EQ-5D-5L). This instrument assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression using one question for each domain. The answers are then translated into the EQ-5D index which ranges from −0.624 to 1 corresponding to very poor and to perfect health-related quality of life, respectively. The EQ-5D instrument further contains a visual analogue scale (VAS), by which subjects estimate their self-rated health from 0 (very bad health) to 100 (very good health) [32].

Cognitive function was assessed using MMSE, a questionnaire with eleven questions designed to assess cognitive impairment and its severity and later progression, which facilitates assessment of changes in cognitive function over time [29,33,34]. The highest possible MMSE score is 30 and classification of the level of impairment has been set as: 24–30 = no impairment, 18–24 = mild impairment, and a score from 0 to 17 = severe impairment [34].

Depressive symptoms among participants were assessed using a variant of the Centre for Epidemiologic Studies Depression (CES-D). This variant (called IOWA) consists of 11 questions (compared to 20 in the original version) [35]. Participant's responses to questions on depressive symptoms were: 1) hardly ever or never, 2) some of the time, and 3) much of the time or always, where they get 0, 1 or 2 points for their answers. A summary score of at least 9 indicates depressive symptoms [35–37].

Body weight was measured in light underwear/clothing on a calibrated scale (model no. 708, Seca, Hamburg, Germany) at discharge and at the participant's homes, and height was taken from the hospital register. Body mass index (BMI) was calculated from the height and weight (kg/m^2).

Dietary intake was assessed using two 24-h-recalls, one at baseline and one at endpoint, to obtain estimates of intakes of energy and energy-giving nutrients [38–43]. The results from the 24-h-recalls were entered into the nutrition calculation program ICEFOOD originally developed for the Icelandic National Nutrition Survey [44]. ICEFOOD relies on the Icelandic database of the chemical composition of food (ISGEM within the Icelandic Medical Directorate of Health) and on a database within the Medical Directorate containing information on several hundred recipes of common dishes and ready-to-eat meals on the Icelandic market [44,45].

Additional variables were collected from the Icelandic electronic hospital registry SAGA (TM software 3.1.39.9), e.g., height, number of ICD-10 diagnoses, and number of different medications. The clinical nutritionist also assessed whether any food-related digestion issues, such as diarrhoea, nausea, constipation, or stomach pain, were experienced during the intervention.

2.8. Sample size considerations

This paper reports results from secondary outcomes of a dietary intervention trial aimed at examining the effect of nutrition therapy on weight change and body composition, as primary outcomes, after discharge from geriatric hospital unit. Accordingly, sample size calculations focused on body weight based on our previous studies on weight change [46,47] and indicated that the number of participants n = 44 in each group was sufficient to detect a body weight difference of 1.8 ± 3.0 kg between groups as significant. The recruitment of >50 participants in each group allowed for more than a 10% drop out while still retaining sufficient statistical power. Post-hoc power calculations showed that the observed power for the four outcome variables of the present paper was between 0.85 and 0.99 (alpha = 0.05).

2.9. Statistical analysis

The data were analysed using statistical software (SPSS, version 26.0, SPSS, Chicago, IL, USA). Normality of data variables was checked using the Kolmogorov–Smirnov test. Data are presented as mean ± standard deviation (SD).

Differences between groups at baseline were calculated using independent samples' t-test (normally distributed variables) or Mann-Whitney-U test (not normally distributed variables) and chi square test for categorical variables.

Because sex distribution was uneven between intervention and controls, despite randomisation, we adjusted for sex in all our outcome analyses using analyses of variance [48]. All effect estimates were reported as means (β) with 95% confidence intervals (95% CI).

To examine whether changes in our outcome variables were associated with changes in body weight due to the intervention, we examined the effect of the intervention across quartiles in body weight change (Q1: −6.4 ± 2.3 kg, Q2: −1.9 ± 1.2 kg, Q3: 0.4 ± 0.5 kg, Q4: 4.3 ± 2.2 kg) and calculated the differences between them in outcome variables using general linear model - univariate. We used contrasts to investigate whether the differences in outcome variables between the quartiles followed a linear trend.

Endpoint calculations represent per-protocol analysis, as dropouts were included only in baseline and not in endpoint analysis. The level of significance was set at $P < 0.05$.

3. Results

During the recruitment period, 1003 subjects were screened. Of these, 106 participants were randomised and participated in the study. Two subjects dropped out during the study period, one from each group (Fig. 1). The study was carried out as planned and all participants in the intervention group received five home visits and three phone calls.

The baseline characteristics of the participants are shown in Table 1. Intervention and controls were similar in most baseline measurements, except for the sex distribution. No major differences in dietary intake at baseline were observed between the two groups (Appendix 2).

During the intervention, dietary intake increased significantly in the intervention group (+937 ± 534 kcal/day, P < 0.001) but decreased in the control group (−832 ± 407 kcal/day, P < 0.001). The control group experienced weight loss (−3.5 ± 3.9 kg; P < 0.001) while the intervention group experienced weight gain (1.7 kg ± 2.5 kg, P < 0.001) (Appendix 2).

In the intervention group, quality of life improved from 0.692 ± 0.147 at baseline to 0.729 ± 0.131 at endpoint but decreased in the control group from 0.682 ± 0.190 at baseline to 0.627 ± 0.225 at endpoint (Appendix 3).

Self-rated health increased in the intervention group from 58.6 ± 20.1 at baseline to 70.1 ± 17.4 at endpoint but decreased in the control group going from 61.2 ± 18.3 at baseline to 54.0 ± 21.5 at endpoint (Appendix 3). Depressive symptoms increased during the study period in the control group going from 5.6 ± 4.7 at baseline to 8.0 ± 4.9 at endpoint, while the corresponding changes in the intervention group were the other way around, going from 5.4 ± 4.2 at baseline to 4.7 ± 3.2 at endpoint (Appendix 3). This resulted in statistically significant endpoint differences between the groups (adjusted in Table 2). The unadjusted baseline and endpoint values of the outcome variables shown for each group can be seen in Appendix 3.

There were significant differences in MMSE, SRH, and CES-D (P < 0.05) between the weight change categories at endpoint (Fig. 2) and the changes in main outcome variables during the intervention were related to changes in body weight in a linear fashion, i.e., MMSE (P < 0.001), SRH (P < 0.001), and CES-D (P = 0.04). However, these associations were not significant for EQ-5D (Fig. 2).

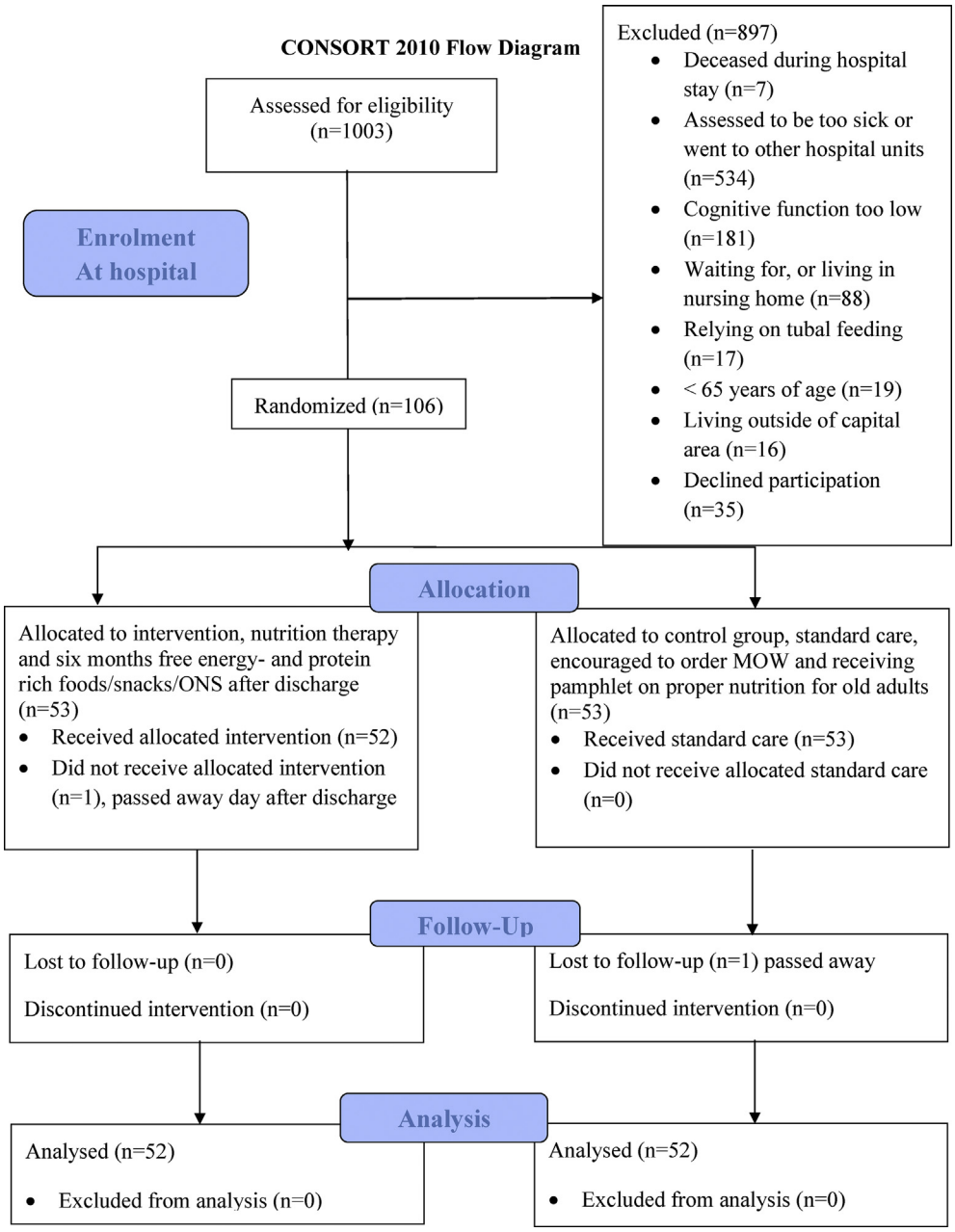

Fig. 1. Flow chart of the intervention study.

Table 1
Baseline characteristics of the study participants stratified by intervention and control.

Variables	Control(n = 53)			intervention (n = 53)			P-value[a]
	mean	±	SD	mean	±	SD	
Age (years)	81.8	±	6.0	83.3	±	6.7	0.228
Female (%)		52.8			71.7		0.045
Higher education (in %)		66.0			69.8		0.677
Lives alone (%)		66.0			66.0		0.999
Alcohol (yes in %)		45.3			37.7		0.430
Smoking (yes in %)		9.4			3.8		0.241
Height (m)	1.7	±	0.1	1.7	±	0.1	0.326
Weight (kg)	76.5	±	19.1	78.3	±	18.3	0.615
BMI (kg/m^2)	26.9	±	5.3	28.5	±	6.5	0.188
SPPB (score)	2.4	±	2	2.5	±	1.8	0.839
ICD-10 diagnoses (no.)	10.5	±	3.8	10.3	±	4.9	0.877
Medications (no.)	12.4	±	4.2	12.2	±	5.8	0.893
MMSE (score)	25.9	±	2.9	26.1	±	2.8	0.702
EQ-5D (index)	0.688	±	0.193	0.694	±	0.146	0.852
Self-rated health (scale)	61.3	±	18.1	58.8	±	19.9	0.493
CES - D (score)	5.6	±	4.7	5.4	±	4.2	0.861

[a] P-value based on chi square test for categorical variables, independent samples t-test for normally distributed continuous variables and Mann Whitney U test for not normally distributed continuous variables. ISNST = Icelandic Nutrition Screening Tool; MMSE = Mini Mental State examination; SPPB = Short Physical Performance Battery; ICD-10 = International Classification of Diseases, version 10; BMI = body mass index. CES-D = Centre of Epidemiological Studies depression lOWA scale; EQ-5D = EuroQol- 5 Dimension quality of life.

No food related issues, such as diarrhoea, nausea, constipation, or stomach pain were reported.

4. Discussion

This secondary analysis of a randomised dietary intervention trial examined the effects of nutrition therapy on cognitive function and mental well-being in older adults discharged from hospital. We found that after six months, cognitive function, self-rated health, depression score, and quality of life improved in the intervention group, while these measures worsened or stagnated in the control group. Further analysis indicated that improvements in most of the outcomes were related to changes in body weight during the intervention, i.e., body weight gain. Something that might also have had a positive effect on the mental well-being and SRH of our intervention group was the support they got from the clinical nutritionist and the delivery staff preventing them from feeling isolated and lonely.

Successful ageing is described by Rowe and Kahn as high physical, psychological, and social functioning later in life without major diseases [49,50]. Thus, cognitive function and mental well-being are all important factors of successful ageing, and observational studies have indicated for a long time that

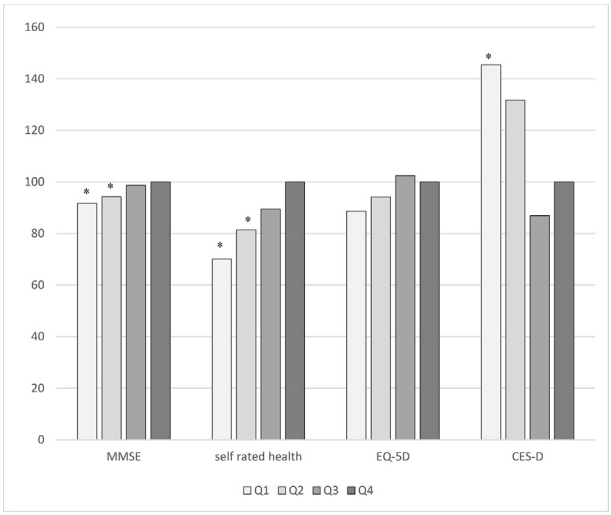

Fig. 2. Percentual differences in MMSE, EQ-5D, self-rated health and CES-D between participants categorized into body weight change quartiles at endpoint of the study. Based on general linear model - univariate. Adjusted for baseline values and sex. MMSE = Mini Mental State examination; CES = Centre of Epidemiological Studies depression scale; EQ-5D = EuroQol - 5 Dimension quality of life; Q1: −6.4 ± 2.3 kg; Q2: −1.9 ± 1.2 kg; Q3: 0.4 ± 0.5 kg; Q4: 4.3 ± 2.2 kg (reference). MMSE, self-rated health, EQ5D index: higher is better; CES-D: lower is better. *P < 0.05, compared to Q4.

malnutrition is associated with poor mental health and cognitive function [5–13]. However, the observational nature of these studies does not allow firm conclusions on the direction of such associations [51].

In general, there is a lack of evidence from intervention studies which are necessary to confirm whether an improvement in nutritional status can increase cognitive and psychological outcomes in older adults. The best evidence available is for quality of life, and a meta-analysis combining results from nine trials showed a significant improvement in physical and mental components of quality of life after nutritional intervention in older adults [13], although only one study included discharged community dwelling older adults [22]. This study by Edington et al., 2004 [22] used the EQ5D to measure quality of life, but did not find significant effects of an intervention on the total EQ5D utility score six-months after discharge using dietary supplements (mean use only for 99 days), although significantly fewer participants in the intervention group reported mobility problems (which is a subscale of the EQ5D) when compared to the control group. In our study, we found significant differences in EQ5D between the groups six months after discharge with better EQ5D in the intervention group. As we delivered food and dietary supplements for the whole study period of six months, this might explain why we found significant an intervention effect and Edington et al. did not, because their intervention span covered only approximately half of the follow-up time.

In general, the available evidence for the effects of dietary intervention on other relevant outcomes such as depression,

Table 2
Estimated differences[a] in MMSE, EQ-5D, self-rated health and CES-D between intervention- and control group at endpoint of the study.

Outcome variable at endpoint	groups	B	95% CI		P-value
MMSE (score)	control vs. intervention	−1.701	−2.563	−0.840	<0.001
EQ-5D (index)	control vs. intervention	−0.102	−0.168	−0.035	0.003
Self-rated health (scale)	control vs. intervention	−15.876	−23.483	−8.269	<0.001
CES − D (score)	control vs. intervention	3.072	1.638	4.507	<0.001

[a] Based on general linear model - univariate. Adjusted for baseline values and sex. MMSE = Mini Mental State examination; CES - D = Centre of Epidemiological Studies depression lOWA scale; EQ-5D = EuroQol - 5 Dimension quality of life. Control n = 52; intervention n = 52.

cognitive function or self-rated health is limited. A recent meta-analysis on the effects of nutrition on depressive symptoms included 16 trials [24]; however, the very different modes of intervention, i.e., weight loss, reduction of fat intake, improvement of nutrition quality, and varying age groups (only three studies [52–54] used exclusively older adults >65 years), do not allow for solid conclusions. Of these three studies investigating older adults, only the study by Endevelt et al., 2011 [54] found that an intensive nutritional intervention program led by a dietitian in malnourished community dwelling older adults positively affected depression. Our study showed significant effects of dietary intervention and depressive symptoms and was similar to the study by Endevlet et al. [54] in several aspects (six months, five home visits), although their intervention included counselling only and did not provide any foods or supplements.

A recent meta-analysis [25] on the effects of nutrition intervention on cognitive function found indications that nutrition intervention can improve some aspects of cognitive functions; however, only two studies included in this meta-analysis used exclusively diet as an intervention in older adults, but did not show significant effects [55,56]. Knight et al., 2016 [55] advised a Mediterranean dietary pattern advised for six months and Mazza et al., 2018 [56] provided olive oil to the intervention group for 12 months. The above-mentioned study by Endevelt et al., 2011 [54] was not included in this meta-analysis [25], however, reported significant improvements in cognitive function after 6 months of intense dietary intervention. Our study agrees with the results from Endevelt et al., showing significant improvements in the intervention group during the 6 months period whereas nearly no change could be observed in the control group.

The evidence on the efficacy of dietary intervention on self-rated health is limited and unclear. Edington et al., 2004 [22] did not find any significant effects of the use of dietary supplements after hospital discharge on self-rated health. On the other hand, the intervention study by Terp et al., 2018 [23] involving several home visits, lead to significant improvements in self-rated health in the intervention group. Our study concurs with the results from Terp et al., 2018 [23] showing a reduction in self-rated health in the control group and an increase in the intervention group leading to significant endpoint differences six months after hospital discharge.

The main finding of the present study is that nutrition therapy, with the aim to prevent malnutrition in older adults discharged from hospital, significantly improved quality of life, self-rated health, depressive symptoms, and cognitive function when compared to current standard care. It is a realistic aim to include nutrition therapy as part of a re-organised home care offering this service to those at nutritional risk to maintain both physical and mental well-being and to potentially reduce reoccurring hospital admissions related to a poor nutritional status.

We found that the observed differences were between 0.6 and 0.8 SD which are considered medium to large effects [58]. The clinical meaning of an observed difference depends on the minimal clinically important difference estimate of an assessment tool [59] which is as follows for our assessment tools: EQ-5D mostly reported between 0.03 and 0.06 [60,61], EQ-5D VAS self-rated health = 8 [62], MMSE = 1–3 [63], and CES-D IOWA = not available [64], indicating that most of the observed differences between the two groups were of clinical relevance.

As our intervention consisted of five home visits by a clinical nutritionist and of weekly deliveries of food items for six months, it can be assumed that improved outcomes cannot be entirely attributed to the increase in dietary intake in the intervention group. Home visits and deliveries likely increased social interactions of participants which have been related to increased quality of life [65], better cognitive function [66], and reduced depression [67] in previous studies. However, we observed that improvements in three of four outcome variables were related to changes in body weight, which indicates that the increase in dietary intake and the associated physiological changes might have contributed to the improved outcomes.

5. Strengths and limitations

It is a strength of the present study that it was a randomised, controlled trial with very low drop out and 100% delivery of the intended intervention to 52 of 53 participants; although it lies in the nature of such dietary intervention studies that participants cannot be blinded to the treatment. Both the time length (six months) and the intensity of the intervention (five home visits, three phone calls, and free home delivered food) were sufficient to induce meaningful effects on the outcomes assessed in this study.

The study size of 106 participants, of which 104 completed the study, was not large enough to balance out all external factors or potential confounders which is reflected in our unbalanced sex distribution across interventions and controls. Nevertheless, adjustment for this imbalance did not indicate that this distortion had a meaningful effect on the outcomes, which is further supported by the fact that our unadjusted (Appendix 3) and sex adjusted results were fully concordant.

It is a limitation of the present study that outcome measurements were conducted at the patients' homes, as we were limited for practical reasons in the time available to conduct a more detailed assessment of, e.g., cognitive function. However, we were still able to collect valuable information on both cognitive function and psychological well-being from which we can draw solid conclusions.

6. Conclusion

Our study shows that cognitive function and mental well-being worsens or stagnates in older adults who receive standard care after hospital discharge. However, a six-month nutrition therapy improves these important determinants of successful ageing leading to clinically significant endpoint differences between the groups.

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Statement of authorship

BSB and AR did the investigation; BSB and AR performed formal analysis; BSB and AR were accountable for project administration; BSB, OGG, AMB, PVJ, TIH, and AR wrote the paper; OGG, AMB, and AR were responsible for conceptualisation; OGG and AR were responsible for supervision; OGG, AMB, PVJ, and TIH reviewed the paper; BSB and AR did the funding acquisition; AR was responsible for methodology.

Declaration of competing interest

The authors declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clnesp.2022.01.010.

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