HOMEFOOD six-month randomised trial

Nutrition therapy including home delivered food for older adults at discharge from hospital

Berglind Soffía Ásbjörnsdóttir Blöndal

Dissertation for the degree of Doctor of Philosophiae

January 2024

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HOMEFOOD sex mánaða slembiröðuð rannsókn

Næringarmeðferð og heimsendur matur eftir útskrift af Landspítala fyrir eldra fólk

Berglind Soffía Ásbjörnsdóttir Blöndal

Ritgerð til doktorsgráðu

Leiðbeinendur

Alfons Ramel og Ólöf Guðný Geirsdóttir

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Ágrip

Bakgrunnur: Vannæring, eða áhætta á vannæringu, er algengt vandamál hjá eldra fólki. Algengi vannæringar eða áhætta á vannæringu er hátt hjá eldra fólki sem dvelst á sjúkrahúsi. En á meðan á sjúkrahúsdvöl stendur og eftir útskrift versnar oft næringarástand eldra fólks, þar sem sjúkrahúsdvalir eru stuttar og oft skortir skimun fyrir áhættu á vannæringu á spítölum. Margar næringarrannsóknir hafa verið gerðar í gegnum árin til að leita árangursríkra leiða til að bæta margvíslegar útkomur fyrir eldra fólk með slæmt næringarástand. Útkomur sem reynt hefur verið að hafa jákvæð áhrif á eru t.d. líkamlegar mælingar, fæðuinntaka, líkamleg geta, vitsmunaleg geta, heilsutengd lífsgæði, þunglyndiseinkenni, fjöldi koma á bráðamóttöku, endurinnlagnir, lengd sjúkrahúsdvalar, þörf á langtímaumönnun (hjúkrunarheimili) og dánartíðni. Niðurstöður úr slíkum rannsóknum hafa verið misgóðar og því var markmið þessarar rannsóknar að kanna hvort hægt væri að hafa jákvæð áhrif á ofangreindar útkomur með íhlutun. Íhlutunin fólst í því að eldra fólk sem bjó í sjálfstæðri búsetu og skimuðust í áhættu á vannæringu fengu næringarmeðferð hjá klínískum næringarfræðingi sem notaði Nutrition Care Process og hugtök þess eftir útskrift af spítala. Ennfremur fól næringarmeðferðin í sér ókeypis orku- og próteinríkan mat, snarl og næringardrykki í sex mánuði eftir útskrift af spítala.

Aðferðir: Alls 106 þátttakendur (≥ 65 ára) af deildum (A1, B4 og L2) Landspítala skrifuðu undir upplýst samþykki. Bakgrunnsmælingar voru gerðar á útskriftardegi og síðan var þátttakendum slembiraðað í tvo hópa; íhlutunarhóp (n = 53) eða viðmiðunarhóp (n = 53). Viðmiðunarhópurinn útskrifaðist á hefðbundin hátt, ásamt því að fá næringarráðleggingar fyrir veikt eða hrumt eldra fólk og hvatningu til að panta heimsendan mat. Íhlutunarhópurinn fékk næringarmeðferð í kjölfar útskriftar frá klínískum næringarfræðingi í fimm skipti á heimili sínu (umönnunaraðilum boðið að vera með) og þrjú skipti í síma. Ásamt því að vera útvegaður ókeypis prótein- og orkuríkur matur, snarl, og næringardrykkir í sex mánuði eftir útskrift. Fæðuinntaka, líkamlegar mælingar, líkamleg geta, þunglyndiseinkenni, sjálfsmat á eigin heilsu, vitræn geta og heilsutengd lífsgæði voru mæld í upphafi og við lok rannsóknar (sex mánuðir). Upplýsingar um komur á bráðamóttöku, endurinnlagnir, lengd legutíma, hvort þátttakandi hefði fengið jákvætt færni og heilsumat og dánartíðni voru fengnar úr rafrænni sjúkraskrá (SAGA).

Niðurstöður: Tveir þátttakendur hættu, einn úr hverjum hóp. Ekki var marktækur munur á orkuinntöku hópanna tveggja við upphafsmælingu (inni á spítalanum) (≈ 1500 kkal/dag). Marktæk aukning bæði á orkuinntöku og líkamsþyngd var í íhlutunarhópnum og minnkun í samanburðarhópnum (+919 kkal/dag, $P < 0.001$ og +1.7 kg, $P < 0.001$ vs - 815 kkal/dag, $P < 0.001$ og -3.5 kg, $P < 0.001$) á rannsóknartímabilinu. Líkamleg geta varð marktækt betri hjá íhlutunarhópnum en stóð í stað hjá samanburðarhópnum á

meðan á rannsókninni stóð. Íhlutunarhópurinn bætti marktækt vitræna getu sína (mælt með Mini Mental State Examination (MMSE)), sjálfsmat á eigin heilsu (SRH) og heilsutengd lífsgæði (mælt með EQ-5D) á meðan á rannsóknartímabilinu stóð, en þunglyndiseinkenni samanburðarhópsins (mæld með CES-D) jukust á meðan SRH þeirra minnkaði. Þetta leiddi til marktæks munar á hópunum tveimur í lokamælingum (6 mánuði), allar íhlutunarhópnum í hag: MMSE: 1.701, P < 0.001; SRH: 15.876, P < 0.001; EQ-5D 0.102, P = 0.001; CES-D – 3.072, P < 0.001. Vitsmunaleg geta, sjálfsmat á eigin heilsufari og bætt þunglyndiseinkenni voru með línulega marktæka fylgni við aukna líkamsþyngd. Við greiningu á gögnum úr sjúkrasögu sáum við að viðmiðunarhópurinn var með marktækt hærra hlutfall af að minnsta kosti einni endurinnlögn samanborið við íhlutunarhópinn eftir 1 og 6 mánuði (15.8% vs 1.9%, P = 0.033; 46.2% vs 25.0%, P = 0.021) en ómarktækt eftir 12- og 18 mánuði (55.8% vs 38.5%, P = 0.051; 65.4% vs 51.9%, P = 0.107). Endurinnlagnir voru marktækt fleiri í samanburðarhópnum í samanburði við íhlutunarhópinn eftir 1, 6 og 12 mánuði (0.19 vs 0.02, P = 0.015; 0.77 vs 0.33, P = 0.014; 1.12 vs 0.62, P = 0.04). Þá var samanburðarhópurinn einnig með marktækt lengri legutíma eftir 1-, 6-, 12- og 18 mánuði (0.92 vs 0.02, P = 0.013; 13.21 vs 2.44, P = 0.006; 19.40 vs 5.83, P = 0.034; 26,00 vs 10,42, P = 0,033). Ekki var marktækur munur á milli hópanna hvað varðar fjölda koma á bráðamóttöku, samþykktu færni og heilsumati eða dánartíðni.

Ályktun: Næringarástand eldra fólks versnar oft eftir útskrift af sjúkrahúsi sem leiðir til verri útkomna, s.s. þyngdartaps, lélegs næringarástands, skertar líkamlegrar getu, vitrænnar skerðingar og verri andlegrar heilsu. Þetta getur svo í kjölfarið leitt til fleiri endurinnlagna og lengri legutíma á spítala. Sex mánaða fjölþætt næringaríhlutun, þar sem eldra fólk í áhættu á vannæringu fékk næringarmeðferð frá klínískum næringarfræðingi, ásamt því að fá ókeypis heimsendan prótein- og orkuríkan mat, snarl og næringardrykki hafði tölfræðilega marktæk jákvæð áhrif á ofantaldar útkomur. Birtingarmynd þessara jákvæðu áhrifa var þyngdaraukning og bætt næringarástand hjá íhlutunarhópi. Þannig gátum við leitt að því líkur að íhlutunin okkar, sem varð til þess að fæðuinntaka varð betri leiddi til tölfræðilega marktækra niðurstaðna á þessum klínískt mikilvægu útkomum. Við mælum með endurskoðun á þjónustu við eldra fólk, þar sem þessari nálgun verði bætt við hefðbundna umönnun eldra fólks sem skimast í áhættu á vannæringu. Enn fremur mælum við með innleiðingu næringarstuðnings, veitt af klínískum næringarfræðingi, og aukinni áherslu á næringaráhættu eldra fólks innan heilbrigðiskerfisins á öllum stigum þjónustu,. Slík inngrip geta haft verulegan ávinning í för með sér fyrir lífsgæði og sjálfstæði eldra fólks, sem og samfélagið í heild sinni.

Lykilorð: Næringarástand, klínískur næringarfræðingur, NCP, fæðuinntekt, líkamsþyngd, líkamleg geta, þunglyndiseinkenni, eldra fólk, vitsmunaleg geta, heilsutengd lífsgæði, endurinnlagnir, lengd legutíma, dánartíðni

Abstract

Background: Malnutrition, or the risk of being malnourished, is a common problem that affects many older adults. This condition is highly prevalent among hospitalised older adults. Because hospital stays are short and screening for nutritional risk at the hospital is rarely done, the nutritional status of this population often continues to deteriorate during hospitalisation and after discharge. Many nutritional intervention studies have been conducted throughout the years to find ways to improve outcomes for older adults at nutritional risk. These outcomes include anthropometric measures, dietary intake, physical function, cognitive function, health-related quality of life, depressive symptoms, number of emergency room visits, readmissions, length of hospital stays, risk of going into long-term care and mortality. Previous findings have been inconsistent; thus, we aimed to investigate whether a nutritional intervention for older adults at nutritional risk, discharging to independent living, could result in positive changes to the abovementioned outcomes. The intervention included nutrition therapy administered by a dietitian using the Nutrition Care Process and its terminology, as well as the provision of free energy- and protein-rich foods, snacks and oral nutrition supplements for six months.

Methods: In total, 106 participants (≥ 65 years) were recruited while hospitalised and signed formal consent. Baseline measures were conducted on the day of discharge and then the participants were randomised into two groups: the intervention group (n = 53) and the control group (n = 53). The control group received standard care (based on the nutritional guidelines for sick or frail older adults and were encouraged to order home-delivered meals). The intervention group received nutrition therapy from a dietitian, according to the Nutrition Care Process, for five sessions at home (caregivers were invited to join) and three sessions by phone. The intervention group also received free protein- and energy-rich meals, snacks and oral nutritional supplements for six months after discharge. Dietary intake, anthropometrics, physical function, depressive symptoms, self-rated health, cognitive function and health-related quality of life were measured at the baseline and at the endpoint (six months). For the secondary analysis of our randomised controlled trial, we collected information from the Icelandic electronic hospital registry on emergency room visits, hospital readmissions, length of hospital stays, whether the participant had received a positive assessment on needing long-term care residency and mortality.

Results: One participant from each of the two groups dropped out. Energy intake did not differ significantly between the two groups (≈ 1500 kcal/day, P = 0.410) at the baseline. A significant increase in both energy intake and body weight was observed in

the intervention group, whereas a decrease was observed in the control group (+919 kcal/day, $P < 0.001$ and +1.7 kg, $P < 0.001$ vs − 815 kcal/day, $P < 0.001$ and -3.5 kg, $P < 0.001$) during the study period. Physical function improved significantly in the intervention group but remained unchanged in the control group during the study period ($P = 0.007$). The intervention group improved their cognitive function (measured with the Mini-Mental State Examination, MMSE), self-rated health (SRH) and health-related quality of life (measured with the EQ-5D) during the study period. However, the control group's depressive symptoms (measured with the CES-D) increased whilst their SRH declined. This resulted in significant differences between the groups at the endpoint, all favouring the intervention group: MMSE: 1.701, $P < 0.001$; SRH: 15.876, $P < 0.001$; EQ-5D 0.102, $P = 0.001$; CES-D - 3.072, $P < 0.001$. Improvements in cognitive function, self-rated health and depressive symptoms were linearly and significantly correlated with the increase in body weight. Through our secondary analysis, we found that the control group had a significantly higher proportion of at least one readmission in comparison to the intervention group at one and six months (15.8% vs 1.9%, $P = 0.033$; 46.2% vs 25.0%, $P = 0.021$) but insignificant at 12 and 18 months (55.8% vs 38.5%, $P = 0.051$; 65.4% vs 51.9%, $P = 0.107$). Readmissions were significantly more frequent in the control group than in the intervention group at one, six and 12 months (0.19 vs 0.02, $P = 0.015$; 0.77 vs 0.33, $P = 0.014$; 1.12 vs 0.62, $P = 0.044$), and the control group also had a significantly longer length of hospital stay at one, six, 12 and 18 months (0.92 vs 0.02, $P = 0.013$; 13.21 vs 2.44, $P = 0.006$; 19.40 vs 5.83, $P = 0.034$; 26.00 vs 10.42, $P = 0.033$). Nevertheless, there were no significant differences between the groups regarding the number of emergency room visits, the need for long-term care or mortality.

Conclusion: The nutritional status of many older adults worsens after hospital discharge, leading to a decline in body weight, nutritional status, physical function, cognitive function and mental well-being, which further leads to an increase in hospital readmissions and longer hospital stays. A six-month multimodal nutritional intervention, providing nutritional therapy by a dietitian applying the Nutrition Care Process and its terminology, along with free protein- and energy-rich foods, snacks and oral nutritional supplements delivered to the participant's home, had significant positive effects on these outcomes. These positive effects were related to the improvement of anthropometrics and nutritional status. First and foremost, we recommend revising the care given to older adults and adding the proposed approach to the standard care of older adults at nutritional risk. Furthermore, we suggest providing nutritional support from a clinical dietitian and raising awareness of nutritional risk among older adults at all levels of the healthcare system. Such an intervention can positively affect the quality of life and independence of older adults and benefit society as a whole.

Keywords: Nutritional status, dietitian, Nutrition Care Process, dietary intake, body weight, physical function, depressive symptoms, older adults, cognitive function, health-related quality of life, readmission, length of hospital stay, mortality

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Berglind Soffía Ásbjörnsdóttir Blöndal.

Contents

List of Abbreviations

24HR	24-hour dietary recall
ADL	Activities of daily living
BMI	Body mass index
CES-D	Center for Epidemiologic Studies Depression Scale
CONSORT	Consolidated Standards of Reporting Trials
DoMAP	Determinants of malnutrition in aged persons
ER	Emergency room
ESPEN	European Society of Clinical Nutrition and Metabolism
GFR	Glomerular filtration rate
HRQoL	Health-related quality of life
ISK	Icelandic krona
ISNST	Icelandic Nutrition Screening Tool
KCAL	Kilocalories
LOS	Length of hospital stay
MMSE	Mini-Mental State Examination
MN	Malnutrition
MOW	Meals on Wheels
NCP	Nutrition Care Process
NCPT	Nutrition Care Process Terminology
NHPAA	Nursing home pre-admission assessment
NT	Nutrition therapy (synonymous with nutritional counselling)
ONS	Oral nutritional supplements
RCT	Randomised controlled trial

SD	Standard deviation
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SPPB	Short Physical Performance Battery
SPSS	Statistical Package for the Social Sciences
SRH	Self-rated health
VAS	Visual analogue scale

List of Figures

List of Tables

List of Original Papers

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals (I, II, III):

III. **Blondal BS**, Geirsdottir OG, Beck AM, Halldorsson TI, Jonsson PV, Sveinsdottir K, Ramel A. *HOMEFOOD randomized trial—beneficial effects of 6-month nutrition therapy on body weight and physical function in older adults at risk for malnutrition after hospital discharge*. Eur J Clin Nutr. 2023 Jan;77(1):45-54. Doi: 10.1038/s41430-022-01195-2. Epub 2022 Aug 26. PMID: 36028775; PMCID: PMC9876791.

II. **Blondal BS**, Geirsdottir OG, Halldorsson TI, Beck AM, Jonsson PV, Ramel A. *HOMEFOOD randomised trial—Six-month nutrition therapy improves quality of life, self-rated health, cognitive function, and depression in older adults after hospital discharge*. Clin Nutr ESPEN. 2022 Apr;48:74-81. Doi: 10.1016/j.clnesp.2022.01.010. Epub 2022 Jan 19. PMID: 35331537.

III. **Blondal BS**, Geirsdottir OG, Halldorsson TI, Beck AM, Jonsson PV, Ramel A. *HOMEFOOD randomised trial—Six-month nutrition therapy in discharged older adults reduces hospital readmissions and length of stay at hospital up to 18 months of follow-up*. J Nutr Health Aging. 2023;27(8):632-640. doi: 10.1007/s12603-023-1962-5. PMID: 37702336.

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Declaration of Contribution

All protocols for the study and applications to the ethical board of Landspitali, The National University Hospital of Iceland, were conducted by the doctoral candidate Berglind S. Ásbjörnsdóttir Blöndal (BSÁB), along with applying for and receiving funding from multiple sources. The doctoral candidate's supervisors Alfons Ramel (AR) and Ólöf Guðný Geirsdóttir (OGG) read through and commented on the applications.

BSÁB took part in developing, planning and conducting the randomised controlled trial (RCT) that served as the basis of this dissertation. This included deciding on the composition of appropriate foods, snacks and oral nutritional supplements for older adults at nutritional risk, provided to the participants in the intervention group. Furthermore, BSÁB was the project manager of the RCT and its assistants. BSÁB screened 1003 potential participants at the hospital where recruitment took place, conducted baseline measures, provided nutrition therapy to the intervention group at their homes five times for a total of 260 home visits, and called participants of the intervention group in between visits to motivate them to follow the prescribed nutrition therapy. BSÁB planned and organised the timing and execution of the mid and endpoint measures of all participants and trained the assistants that conducted the measures.

BSÁB supervised all data collection and input of said data, along with an independent researcher. BSÁB was involved in the statistical analysis and the writing of Papers I, II and III as well as their revision and submission.

BSÁB participated in multiple congresses; in some of them, the presentation was in the form of a poster and in others, it was an oral presentation.

During her time as a PhD student, BSÁB was a research assistant in an unrelated study, SPRINTT, where she conducted measurements, developed questionnaires and provided lessons to the participants, activities that strengthened her skills in conducting the RCT. BSÁB gave many lectures in various courses taught in the Faculty of Food Science and Nutrition and the Faculty of Health Sciences of the University of Iceland. She also taught the clinical guidelines for nutrition for frail or sick older adults to paramedics. In addition, she co-supervised the final research projects of five MSc students. BSÁB was a member of the PhD student council from the fall of 2020 to the spring of 2022.

1 Introduction

Older adults, a growing population in Iceland as in other countries worldwide, are frequently undernourished when admitted to the hospital due to various reasons (1). Hospital stays tend to be short, not allowing for the necessary time to correct the nutritional status of patients, which often worsens during their stay and further declines after discharge (2). Thus, providing nutritional therapy (NT) to improve the nutritional status of those at risk of malnutrition is of utmost importance to prevent the negative consequences of a lack of nutrients on both physical and mental health and to maintain the skills necessary for independent living (3, 4).

The first task that needs to be addressed is that older adults at nutritional risk need to be identified because, without this knowledge, it is impossible to find and utilise ways to correct nutritional issues. Once those at nutritional risk have been identified, proper treatment needs to be implemented by following guidelines founded in scientific evidence, showing what measures are most effective to improve the nutritional status depending on individual circumstances (4).

According to the clinical guidelines on nutrition, both in Iceland and throughout the world, older adults should be screened for nutritional risk, using a validated screening tool on admission to the hospital and during the hospital stay (4-6). All older adults should be screened, not only in the hospital but in all sectors of the healthcare system, because malnutrition affects all aspects of health, and does not manifest exclusively while hospitalised (4-6). Involuntary weight loss, a contributing factor to malnutrition, is not always present in older adults at nutritional risk or malnourished, but when present, it should be identified early to be able to halt this process by providing adequate energy intake with foods appropriate to the affected individual (7). To prevent weight loss in older adults, the cause/s behind it should be identified and addressed, while simultaneously providing the necessary means to meet individual energy and protein requirements (7-9). Weight can be measured easily and monitoring it is crucial to prevent weight loss, which is an indicator of worsening ability to perform activities of daily living (ADL) (10).

Weight loss leads to negative outcomes for older adults, such as a weakened immune system, loss of lean body mass, loss of physical function and declining mental well-being (8). A poor nutritional status before, during and after hospitalisation that results in the loss of lean body mass can lead to a

regression in physical function, which is crucial to be able to maintain independence in older age (11, 12). This is of great clinical relevance as the independence of older adults relies on maintaining muscle mass and being able to perform ADL (11).

The 2019 European Society of Clinical Nutrition and Metabolism (ESPEN) guidelines on clinical nutrition and hydration in geriatrics recommend that appropriate nutritional support should be provided, if necessary, during hospitalisation and should be continued after discharge if the nutritional risk is present (4). This is further emphasised and confirmed in the 2022 ESPEN practical guidelines on clinical nutrition and hydration in geriatrics (10).

Previous intervention studies of varying lengths (2–12 weeks) have not been able to show substantial effects of providing either oral nutritional supplements (ONS), Meals on Wheels (MOW) or NT by a dietitian on the nutritional status of patients (9, 13-15). Thus, there is a need for an intervention lasting for a longer period, with many components put together to elucidate the effects of energy and protein intake on body weight (i.e., to prevent unintentional weight loss) as no studies have been carried out using the abovementioned nutritional tools combined for a longer period of time (24 weeks).

This situation led us to design and perform a six-month randomised controlled trial (RCT) for older adults discharged home from the hospital. The participants in the intervention group received NT by a clinical dietitian, based on the principles of the Nutrition Care Process (NCP) and the Nutrition Care Process Terminology (NCPT), and were provided protein- and energy-rich meals, snacks and ONS. Meals and snacks were ensured to be both traditional and to the liking of older adults in the Icelandic population. The intervention lasted for 24 weeks, and our intention of providing free food, NT and having it last for this long period was to determine whether it would minimise weight loss, prevent muscle deterioration, and thus provide the participants with the best chance of maintaining or improving their physical function **(Paper I)**.

For the older adult, certain physical abilities alongside mental and/or social functions can decline when a chronic or acute disease is present and be further exacerbated by the deterioration that occurs with ageing (4).

Maintaining physical function is important, but equally important is maintaining or improving the psychological and mental health of older adults, where an adequate nutritional status is a key component (16), thus providing the best chance of having a good health-related quality of life (HRQoL).

Studies have shown that an adequate nutritional status, including an appropriate intake of energy and protein, can alleviate the negative consequences of malnutrition/undernutrition on physical and psychological

well-being (8, 17). To evaluate whether interventions have a positive effect on the mental well-being of participants, a questionnaire for HRQoL is often used. The questionnaire contains a visual analogue scale (VAS) for self-rated health (SRH) that has been shown to predict mortality risk, both in the short and long term and provides an indication of how a person perceives their health (18-20).

The Mini-Mental State Examination (MMSE) is often utilised to evaluate cognitive function (21). To measure depressive symptoms, a questionnaire known as the Center for Epidemiologic Studies Depression Scale (CES-D) is used (22). Because mental health is equally important for the overall well-being of older adults, we wanted to ascertain whether the provision of our intervention could not only improve the physical aspects of these individuals but also improve the participants' HRQoL, depressive symptoms, SRH and cognitive function **(Paper II).**

The association between malnutrition and adverse outcomes (e.g., increased emergency room (ER) visits and hospital readmissions, increased length of hospital stay (LOS), increased mortality and increased need for long-term care residency) is well-known (23, 24). These outcomes are costly to the individual, the healthcare system and society. Thus, finding ways to prevent the undernourishment of older adults is something the whole community should strive for.

Furthermore, supplying and implementing proper NT to those undernourished or malnourished to achieve clinically significant and cost-effective results is of utmost importance (4). Hence, we also investigated whether our intervention could reduce ER visits and hospital readmissions, shorten LOS and decrease mortality during the intervention phase and at one, six and 18 months, even though the intervention was only provided for six months **(Paper III).**

The present doctoral dissertation aimed to investigate the effects of an intense nutritional intervention on the nutritional status of community-dwelling older adults at nutritional risk. Furthermore, we evaluated whether the NT affected the mental and physical well-being of the participants. The NT was provided by a dietitian and included free energy- and protein-rich food, snacks and ONS after hospital discharge. We evaluated whether the intervention could decrease LOS, the rate of ER visits, readmissions, nursing home admissions and mortality.

2 Background

2.1 Older adults

Older adults are often defined as individuals who have reached the age of 65 (4). According to the Statistics of Iceland website, older adults are defined as being 67 years or older and they made up 14.9% of the Icelandic population on January 1st, 2022, with an estimated increase to 21.7% by 2050 (25). During the ageing process, the disease burden increases and physical, social and mental changes occur, affecting the nutritional status and increasing malnutrition in the older adult (26). Physical decline can result in a lessened ability to perform ADL, as it can have a direct effect on the ability to provide oneself with adequate nutrition, for example, by making it difficult to shop for groceries or to be able to feed oneself adequately (both the mechanics of getting food to the plate and from the plate to the mouth may be impaired) (26). These and other factors, along with the facts that, with increasing age, the bioavailability of certain nutrients decreases, hunger signals decline, and the requirements for protein and certain vitamins and minerals increase, elevate the chances of being at nutritional risk (27).

2.1.1 Community-dwelling older adults

Iceland has, on average, a younger population than the rest of Europe. In 2020, Icelandic older adults (> 65 years) accounted for 14% of the total population but this percentage rose to 20% on average in Europe (28). Iceland's total population in 2020 was 364,134, of which 50,9179 were over 65 years old (28). In Reykjavik and its surrounding area, the total population was 216,878 in 2017, and of those, 25,382 were ≥ 67 years old according to a report published by the Institute of Social Sciences of the University of Iceland (29). According to that report, people ≥ 67 years old comprise 11.7% of the total population in the area, and of those, 6147 (24.2%) receive formal care, meaning that they have started to decline in some areas of ADL (29). For the same year (2017), data on the Statistics of Iceland website indicated that 1405 of the 6147 individuals who received formal care, received both social care and nursing care at home, which made them the most vulnerable part of the population (30). A report from the Icelandic Ministry of Finance and Economy, published in 2022, about the services that older adults use and about the utilisation of the budget provided for said services, recommended focusing on prolonging independence to prevent early nursing home admission and hospital stays (31). These recommendations are based on the cost of different

healthcare services. The annual cost in 2022 for hospital services for older adults was ≈ 71 billion Icelandic krona (ISK), of which ≈ 48.8 billion ISK were for hospital stays; the cost for nursing homes was ≈ 15.2 billion ISK, the cost for day-stay centres was ≈ 4.3 billion ISK and the cost of formal care rendered by social services and/or nursing homes was ≈ 2.0 billion ISK (31).

2.2 Malnutrition

Malnutrition is a well-known and ubiquitous problem in older adults. Different terms for malnutrition in older adults are present in the literature.

One of these terms, protein-energy malnutrition, refers to the state when there is a lack of calories and/or proteins consumed, digested or absorbed properly to fulfil a person's needs (32-34).

In the ESPEN guidelines on definitions and terminology of clinical nutrition, malnutrition is described as a state where unintentional weight loss, wasting and deficiencies of macro- and/or micronutrients can occur, and is a nutritional disorder synonymous with undernutrition (35). The malnutrition older adults experience is further divided into three subcategories according to their causes (35):

- Disease-related malnutrition driven by inflammation.
- Disease-related malnutrition without any known inflammation.
- Starvation-related malnutrition from either hunger, psychological or socioeconomic factors, without the presence of disease.

Because malnutrition is highly prevalent among older adults in the form of undernutrition as described by ESPEN, malnutrition is the term that will be used throughout this dissertation to cover both undernutrition and protein-energy malnutrition as these are the most frequent types of malnutrition in the studied population (i.e., community-dwelling older adults discharged from hospitals) (36).

2.2.1 Definition

ESPEN defines malnutrition (undernutrition) as:

'A state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat-free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease' (37).

2.2.2 Causes and risk factors

The causes of malnutrition in older adults are usually multifactorial and complex as many aspects contribute to and drive the progression of malnutrition (8).

The main challenge in identifying the causes of malnutrition is that it can originate from the interaction of physiological, psychological, social, economic and environmental sources, further complicating the efforts to combat this serious health problem (33).

The multifactorial causes of malnutrition are listed in a recent paper by Volkert et al. (27) Figure 1 was taken from that paper and illustrates these multifactorial causes and their interactions:

Figure 1 – DoMAP model

All factors—independent of the level—are regarded as (potential) 'determinants' of malnutrition (MN), meaning that they may contribute to the development of MN in a causative manner. The levels illustrate different modes of action:
Level 1 (dark green): Central etiologic mechanisms.
Level 2 (light green): Factors at this level directly lead to one of the three mechanisms in Level 1 (e.g., swallowing problems may directly cause low food intake).
Level 3 (yellow): Factors at this level may indirectly lead to one (or more) of the three central mechanisms through one (or more) of the direct factors in the light-green triangle (e.g., a stroke may cause low food intake via dysphagia or difficulties with eating).
Surrounding factors in red are age-related changes and general aspects, which also contribute to the development of MN but act even more indirectly or subtly.
DoMAP = Determinants of malnutrition in aged persons; MN = malnutrition (27).

With increasing age, the chances of having multiple interacting causal factors increase, as do the chances of having multiple chronic conditions simultaneously, making the NT provided by a dietitian complicated and the need for individualised NT even greater (27).

One of the causal factors responsible for the insufficient protein intake of older adults is the change in the eating patterns of this population, from a varied diet rich in protein to a monotonous, carbohydrate-rich diet (38). This, in conjunction with a probable increased need for protein, substantially increases the risk of malnutrition, which then elevates the risk of losing muscle mass and can further lead to a loss of physical function (8).

2.2.3 Consequences

In older adults, being malnourished and having increased catabolic pathways due to ageing or ageing and disease combined results in exacerbated malnutrition (39).

Some of the consequences of malnutrition in older adults are listed below (8, 27, 40):

- Fatigue
- Impaired immune function
- Impaired physical function
- Increased mortality
- Poorer HRQoL
- Increased LOS
- Increased length of any type of rehabilitation
- Higher hospital admission or readmission rates
- Higher rates of complication during hospital stays
- Higher hospital costs
- Increased risk of depression and anxiety
- Social isolation

These consequences lessen HRQoL, affect mental and physical health and are costly to the affected individual and the community.

2.2.4 Prevalence

The prevalence of malnutrition among older adults in nursing homes, acute hospital care and rehabilitation settings is reported to be around 50%, whereas the prevalence among community-dwelling older adults is estimated to be around 10% (41-47). Hospital patients have a high prevalence of malnutrition,

which varies for different groups, hospital wards and countries. In the acute care setting of hospitals, the prevalence of malnutrition is as high as 45% (1, 48-50). In Iceland, the prevalence of malnutrition in a hospital setting is estimated to be between 49% and 66% (51-53). According to a literature review published in 2020 (1), the detrimental consequences of a poor nutritional status upon hospital admission—which often worsens during the hospital stay—are, for example, an increased LOS (1, 54), a higher incidence of medical complications (1, 55), increased readmission rates (1, 56), an increased mortality rate (1, 55) and an increased risk for mortality for up to 4.5 years after discharge from hospital (1, 57).

2.2.4.1 Prevalence of malnutrition in hospitalised older adults

The highest prevalence of malnutrition in hospital patients is observed among older adults. Not only is the percentage of malnourished geriatric patients high but, during their stay and after discharge home, their nutritional status often worsens (58).

The prevalence of malnutrition among older adults differs among countries. In Asia, the prevalence has been reported to be between 16% and 78% (59-65), whereas, in the United Kingdom, the prevalence has been reported to be between 29% and 61% (66, 67).

In a 2019 systematic review and meta-analysis, the prevalence of being at risk or high risk of malnutrition was 43–78.5% for European hospitalised older adults (68).

In Iceland, the risk of malnutrition among older adults is also high, ranging from 23% (69, 70) to 66% (51, 53, 71). Those at risk of malnutrition are so at admission and often worsens during the hospital stay, which is usually short, not allowing much time for correcting the nutritional status before discharge. The nutritional status of the older adult after discharge will often decline further. This trajectory is something that needs to be addressed by greater coordination among all stages of healthcare, starting with early screening for nutritional risk in all healthcare settings, followed by individualised NT (51, 71). Furthermore, the current discharge practice in Iceland is to recommend that the older adult orders MOW, but otherwise, there is no nutritional follow-up by a dietitian, which contrast with to the current recommendations given by ESPEN for the nutritional care of discharged nutritionally at-risk older adults (10).

2.2.5 Screening for risk of malnutrition

Malnutrition should be prevented before it occurs or treated as soon as it is discovered as the many consequences of this condition are serious and affect

sufferers both mentally and physically (8, 40). To identify those at nutritional risk, nutrition organisations worldwide recommend the use of a validated screening tool (4, 5, 72, 73). Unfortunately, implementing this simple step in the identification of those in need of nutritional support has had little success (1, 74).

Good nutritional practices are illustrated in Figure 2 (76):

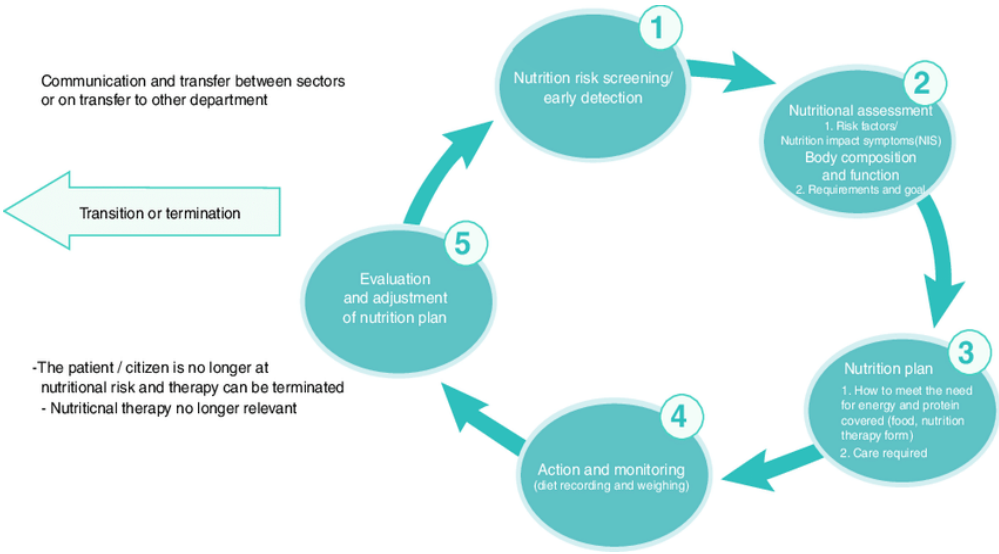

Figure 2 - The Multiprofessional Nutrition Care Process model.
(Model by Mette Holst; reprinted from an article published under an open-access Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/) with no changes made to the figure).

According to the ESPEN guidelines on clinical nutrition and hydration in geriatrics (4), nutritional screening should be performed regularly and on admission to the hospital. If nutritional risk is detected, a full assessment of present nutritional problems should be performed to be able to provide an intervention addressing them. Furthermore, monitoring the nutritional status is necessary to ensure that the implemented intervention is successful and to be able to make appropriate adjustments if the intervention is not delivering the desired results (73). If malnutrition is left without proper nutritional interventions, weight loss can occur, leading to a loss of lean body mass. This negatively impacts physical function and, in turn, the ability to perform necessary ADL (10, 39). Furthermore, the impact of this trajectory worsens when older adults fall ill and spend more time bedridden (e.g., while hospitalised), which can exacerbate the consequences of malnutrition (39, 75).

According to the Icelandic clinical guidelines on nutrition for patients, screening for malnutrition should take place on hospital admission and every

1–2 weeks during the hospital stay if a low risk of malnutrition is detected (5). If a risk of malnutrition is present, re-evaluation should take place every 2–4 days, and if a high risk of malnutrition is present, re-evaluation should take place every 1–2 days (5). When screening for malnutrition risk, the validated Icelandic Nutrition Screening Tool (ISNST) should be used (5). The clinical guidelines should also be applied to determine the course of action required according to the outcome of the screening (5).

The measures included in the ISNST are summarised in Table 1.

Table 1 – Measures listed on the Icelandic Nutrition Screening Tool (ISNST)

Measures/symptoms	**Unit/selection**	**Score**
Height (cm)	cm	
Weight (kg)	kg	
BMI*	kg/m^2	0–4
Weight loss	yes/no	
Amount (kg)	kg	
Over how long (months)	months	
Body weight lost (%)	%	0–4
Older than 65 years	yes/no	1
Daily vomiting for more than three days	yes/no	1
Daily diarrhoea	yes/no	1
Prolonged poor appetite or nausea	yes/no	1
Dysphagia or difficulty chewing foods	yes/no	1
Hospital stays for > 5 days in the past 2 months	yes/no	1
Undergone major surgery in the past month	yes/no	1
Suffered burns >15% of the body	yes/no	5
Hospitalisation due to malnutrition	yes/no	5
Multiple trauma	yes/no	5
Total score		**0–30**

*BMI = body mass index

Interpretation of score:

0–2 points = Low risk of malnutrition

3–4 points = Risk of malnutrition

≥ 5 points = High risk of malnutrition

For patients scoring 0–2 points, and thus at low risk of being malnourished, their food should remain unchanged (5). Re-evaluation should take place every week and sooner if (5):

- ¾ of the energy and protein needs are not met for over a week.
- 0.5–1.0 kg weight loss/week is detected.

Those scoring 3–4 points and therefore at risk of being malnourished should (5):

- If able to eat orally, obtain the usual food, energy- and protein-rich foods and perhaps ONS.
- If unable to eat orally, enteral or parenteral nutrition should be provided until oral feeding is possible.
- If the provision of protein- and energy-rich food and ONS fulfils the patient's needs, it should be continued.
- If this is not successful, ONS and enteral nutrition should be added; if this is still insufficient, parenteral nutrition should be added to the NT.
- These measures are to be followed until the patient is no longer at risk of malnutrition.

Those scoring ≥ 5 should, along with the measures listed above, also receive NT provided by a dietitian (5).

Although screening and early detection of malnutrition risk is recommended by nutrition societies, is incorporated into clinical nutritional guidelines and is also an important first step in combatting the prevalent and grave problem of malnutrition among older adults, efforts to implement it in the clinical practice have been largely unsuccessful (77-79). The general absence of training and nutrition education among healthcare providers may be a factor that hinders the screening for malnutrition and early diagnosis as many practitioners are unaware of this problem. This lack of awareness contrasts with the high prevalence of malnutrition and its dire effects on the health of those affected, resulting in high costs for the healthcare system (80).

2.3 Nutrition therapy

The ESPEN practical guidelines on clinical nutrition and hydration in geriatrics recommend that a dietitian providing NT should utilise a broad range of NT tools (10). These tools include written advice, calls to check up on any progress, ensuring that the prescribed NT is well tolerated, and using foods and snacks that are modified to fulfil the patient's needs (however, this recommendation has not been studied thoroughly and is based on clinical experience) (10).

The ESPEN guidelines recommended that, as a first step, an individualised NT should be provided by a dietitian to older adults at risk of malnutrition (or already suffering from the condition) to improve their nutritional status (10). The ESPEN guidelines also point out that important factors of an NT include teaching the affected individual about their nutritional needs on an individualised basis, where the dietitian supports the individual to strengthen their nutritional knowledge to be able to take care of their nutritional needs (10, 81, 82).

To ensure that the NT is delivered and is supported by those taking care of the older adult, the caregivers (formal and informal) should be offered to take part in the NT sessions to increase the chance of adherence to the proposed NT and to be able to fulfil the nutritional needs of the nutritionally at-risk person (10). This recommendation is based on studies showing that NT used to prevent or combat malnutrition should include several sessions where the at-risk older adult and their caregivers are properly educated about the importance of the food required to improve the nutritional status of the former (81, 82).

These recommendations of an individualised NT are based on a Danish national clinical guideline for nutrition and training initiatives aimed at older adults with geriatric issues (83) and a systematic literary review by Munk et al. (84). Both examined which effects an individualised NT has on nutritionally at-risk or malnourished older adults. The Danish guideline found four heterogeneous and low-quality studies (85-88) with no significance on the effect of interest (mobility) when summarising the findings and conducting a meta-analysis. The guideline did, however, show trends favouring an individualised NT for desired outcomes such as body weight and protein and energy intake. Moreover, the guideline indicated that the NT intervention should be provided for at least 12 weeks when implemented for positive results (83).

The systematic literary review by Munk et al. focused on NT in older adults at nutritional risk after hospital discharge and included four RCTs (85, 89-91). They were all deemed to have a high risk of bias and the intervention methods were heterogeneous (84). The RCTs mainly differed in when, the time and number of the NT sessions provided, what they included, and whether ONS or vitamins were prescribed (84). The meta-analysis showed an improvement in energy and protein intake and body weight but no improvement in other measures (84).

This ESPEN recommendation on individualised NT is further supported by more recent findings, some of which are mentioned below:

- A 2019 pooled analysis of nine RCTs on dietary NT interventions, authored by Reinders et al. (36). The RCTs that provided nutritionally at-risk older adults with NT including the provision of ONS were the most successful in positively affecting energy intake and body weight (36).
- A systematic review and meta-analysis by Wong et al. (92) that looked at the effects of NT, with or without nutritional supplementation, on hospitalised patients who were malnourished or at risk of malnutrition and after discharge, found positive effects

(reduced complications). The authors found no effect on mortality at 30 days, but a slight reduction in mortality at six months and in readmissions (92). They did not find a reduction in LOS compared to standard care, and the effects on HRQoL were unclear. Wong et al. pointed out the need for high-quality studies with standardised NT and educational methods, as well as a standardised length of the intervention and frequency of NT. Moreover, the reporting details of the provided intervention (ONS, NT, education and adherence) should be standardised in future studies to be able to determine the effects of NT (92).

- Baldwin et al. published a Cochrane review in 2021 where they assessed the effects of NT alone or NT + ONS on adults with disease-related malnutrition or who were at nutritional risk (93). The authors wanted to determine whether NT or NT + ONS interventions could improve survival, body weight and HRQoL (93). A total of 94 studies with heterogeneous participants, interventions and settings were included. These studies were at risk of bias and had a high statistical heterogeneity, resulting in low evidence for most of the analyses (93). The authors were unable to find any type of intervention effect on mortality but found positive effects on body weight with NT and NT + ONS interventions. Other outcome analyses were unclear (93). Baldwin et al. argued that more studies where the affected individual is the focus and more healthcare outcomes are reported are needed to fully answer the questions asked in their review (93).

Even though the abovementioned studies mostly agree with the ESPEN guidelines, there is a knowledge gap that needs to be addressed when it comes to nutritional interventions implementing NT. Knowledge about the impact of NT applying the NCP and all the tools it provides is lacking. Thus, using the NCP and reporting the use of it in RCTs would be valuable to ensure that a standardised NT method is provided.

This is among the topics of a paper by Volkert et al., focusing on the management of malnutrition in older patients (11). The authors suggested that the best methodology for providing NT should be the most fitting and cost-effective way according to the type of patient and the care setting (11). This along with the appropriate timing, repetition and timing of follow-ups of the provided NT needs to be clarified.

Moreover, Norman et al. conducted a comprehensive review that summarised current evidence on malnutrition in older adults and concluded that studies so far show conflicting evidence regarding the effects of NT (24).

2.3.1 Nutrition Care Process

The NCP was introduced by the House of Delegates of the Academy of Nutrition and Dietetics in 2003; it is the state of the art in nutrition care. The use of the NCP ensures high-quality care and helps dietitians using it achieve consistency and predictability for the desired outcomes in individual care. NCP has its own terminology, NCPT, to ensure a unified language in NT. The NCP is a consistent process, enabling the dietitian to provide tailored care to each patient in a methodical way, according to the latest scientific evidence in nutrition science (94).

There are four steps in the NCP that connect with each other (94).

1. Assess the patient by collecting information on eating habits, diseases, gastrointestinal symptoms, biochemical data and anthropometric measures.
2. With the information collected in the assessment phase, the dietitian can progress to the next step, where the appropriate selection of a nutrition diagnosis takes place using the NCPT.
3. Based on the diagnosis, the dietitian selects the most appropriate nutrition intervention for a particular case, with the aim of relieving the patient's symptoms.
4. The fourth step is to plan a follow-up of the patient, which will be the guide to the next appointment where the dietitian can monitor and evaluate whether the intervention has delivered the intended results. This last step can then lead to either the resolution of the problem or a new nutrition diagnosis to be addressed.

These four steps are always being re-evaluated by the dietitian and can involve several cycles depending on the nutritional issues of the patient. Thus, the circular model of the NCP is used to represent the process (Figure 3) (94). When using the NCP, the dietitian ensures that the client obtains an individualised approach and that all nutrition-related problems are tackled according to their priority, where the nutritional issue causing most of the problems for the client is addressed first (94).

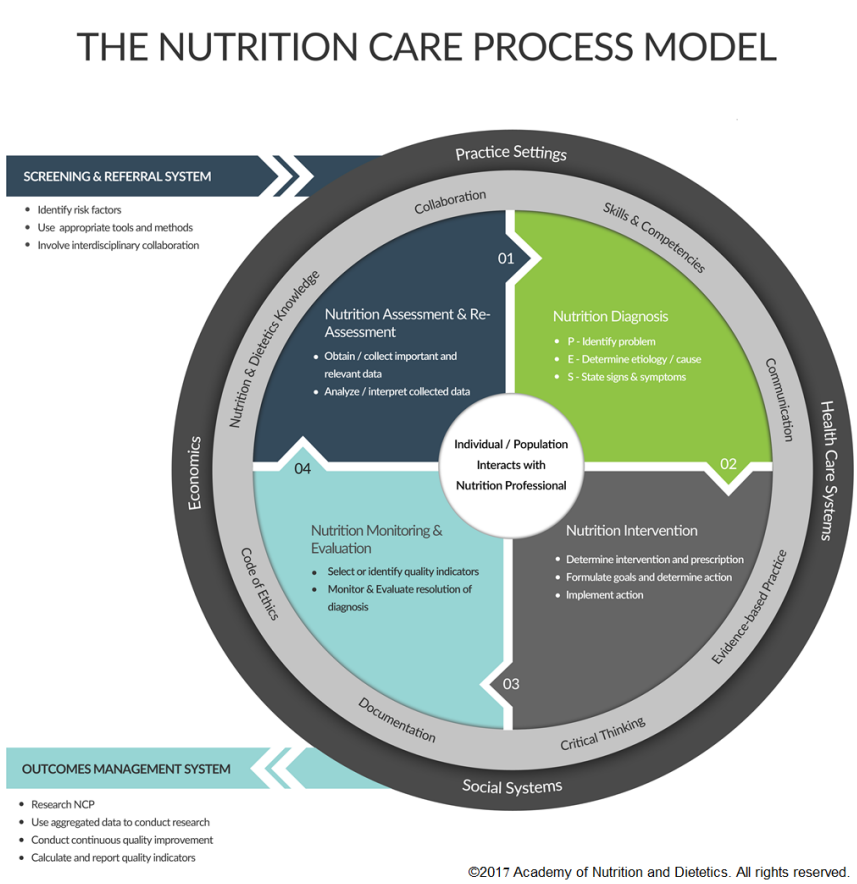

Figure 3 - Schematic representation of the Nutrition Care Process.

(Reprint from the Journal of the Academy of Nutrition and Dietetics, 117(12) William I. Swan, Angela Vivanti, Nancy A. Hakel-Smith, Brenda Hotson, Ylva Orrevall, Naomi Trostler, Kay Beck Howarter, Constantina Papoutsakis. Nutrition Care Process and Model Update: Toward Realizing People-Centered Care and Outcomes Management p. 2003–2014. Copyright (2017) with permission from Elsevier).

The utilisation of NCP enables the dietitian to work with the personal preferences of the client, which makes any nutritional intervention more likely to succeed and increases the likelihood of improving the nutritional status of the client (95). Not many studies have specified or included NCP in their interventions, and we did not find any report on older hospitalised adults. One study suggested that providing cancer patients with cachexia access to a dietitian applying the NCP can greatly improve nutritional outcomes (96). The NCP provides the dietitian with an important tool to follow up on the diagnosed nutritional problem until it is resolved by having specific goals and documenting them (80).

The lack of studies where NCP is either used by the dietitian or mentioned in the methodology, NCP has never been part of a nutritional multimodal intervention in Iceland. Thus, it was of great value to have the opportunity to individualise the intervention in this methodical way.

2.3.2 Protein- and energy-fortified foods and snacks

2.3.2.1 Fortified food

The 2022 ESPEN practical guidelines on clinical nutrition and hydration in geriatrics (10) recommend that older adults who are either at nutritional risk or malnourished should be provided with fortified food to ensure that their protein and energy needs are met. This recommendation is based on two systematic reviews. One systematic review investigated the effects that enriching conventional foods for nutritionally at-risk older adults would have on energy and protein intake (97). That review included nine studies that indicated that the enrichment of foods had a positive effect on the energy and protein intake of older adults, although other outcomes were not assessed (97). The other was a systematic review and meta-analysis that was the basis of this ESPEN recommendation; the review included seven studies with a total of 588 participants and a meta-analysis of four of the studies that showed statistically significant results on both protein and energy intake (98). Both systematic reviews pointed out that even though fortification of foods can increase protein and energy intake, this finding is based on a few studies and more high-quality research is needed (97, 100). To ascertain whether more recent findings on the fortification of foods for malnourished (or at nutritional risk) older adults were available to support the recommendation in the ESPEN guideline, we conducted an extensive search to gather reviews, meta-analyses and/or RCTs from 2016 to the present day because the search for the ESPEN guideline-based recommendation was conducted pre-2017. We found that:

- Moloney and Jarrett performed a scoping review in 2021, where one part of their research question was to identify nutrition intervention studies with the intent to prevent or treat malnutrition in older adults (99). Two studies on home-dwelling older adults who were provided fortified and/or densified foods, published after 2016 (and which were not included in the ESPEN guidelines), were identified through their review:
    - A 2018 pilot study by Arjuna et al. that recruited older adults among MOW recipients who were at nutritional risk by advertising on community boards (100). These authors found a significant improvement in the energy and protein intake and nutritional status of the participants who received the intervention (n = 12), which provided densified and protein-

rich meals at least three times per week for 12 weeks plus NT. This contrasted with the non-significant changes in the nutritional status of the other two groups in their study: a control group (n = 10) and a group that only received NT (n = 7) (100).

- A 2017 RCT by Beelen et al., where they provided protein-fortified foods for 12 weeks to their intervention group (n = 36) after discharge home from the hospital. The control group (n = 39) received food for 12 weeks, without protein fortification (101). The authors found that protein fortification resulted in a significantly higher protein intake in the intervention group, however, other outcomes did not differ between the groups (101).

Other studies were found by checking the references, or were recommended articles featured in PubMed:

- In 2019, Dent et al. reviewed approaches to provide older adults with sufficient protein, energy and micronutrients (102). These authors recommended the implementation of early interventions to prevent malnutrition before it occurs because even intense nutritional support might not be successful if a substantial amount of weight has been lost already (102). They recommend the fortification of foods and/or snacks palatable to older adults as a first line of defence (102).
- Ziylan et al. conducted a double-blind RCT that lasted for two weeks, where they provided the intervention group with protein-enriched bread and ready meals, resulting in an increase in the protein intake of community-dwelling older adults (103). They highlighted that their study had few participants (n = 22 in the intervention group; n = 20 in the control group) who were reasonably healthy; thus, the results may have differed had intervention been performed on frail or sick adults (103).
- In 2021, Sossen et al. conducted a systematic review and meta-analysis to determine whether fortification and densification of foods and/or drinks within a nursing home setting could increase the energy and protein intake of the residents (104). These authors included 16 studies, 13 of which were used for the meta-analysis, where a statistical difference was found in both the energy and protein intake when the standard diet of the nursing home residents was fortified (104).
- An RCT by Borkent et al., where protein-rich meals and dairy products were provided to the intervention group (n = 49) for 29 days, resulted in significant improvements in protein intake compared to the control group (n = 49) (105). The authors emphasised that when the provided foods are not energy-rich, there is a chance of lower calorie consumption and that neither group met the target protein intake of 1.2

g/kg body weight/day (105). As the need for protein is thought to increase with age, Borkent et al. called for protein fortification of foods provided for older adults, along with energy enrichment (105).

- The Nutrition Society (a London-based society in the field of nutritional science) published a review of the nutritional challenges of European older adults, where they compared data from 18 countries and long cohort studies, and recommended the fortification of food for this age group because older adults find it difficult to fulfil their protein and energy needs (106).

Protein requirements are thought to increase with age; thus, a higher protein intake has been recommended for older adults by several countries and nutrition expert groups (10, 107-110). However, there are disagreements, and Hengeveld et al. argued that this might not be the case (111). These authors conducted a systematic review and found that higher protein intake might have positive effects on lean body mass and muscular strength (but only when combined with exercise) and not on physical performance or bone health (111). These authors were unable to clarify other outcomes because of the lack of enough RCTs. Hence, they were unable to recommend an intake of protein higher than the recommended 0.8 g/kg body weight/day for older adults (111).

Therefore, the abovementioned reports and the ESPEN practical guidelines on clinical nutrition and hydration in geriatrics provide enough evidence to safely recommend that, at least those older adults at nutritional risk or with malnutrition, should adopt a protein- and energy-rich diet, and receive such if hospitalised, in nursing homes or receiving home-delivered meals.

2.3.2.2 Fortified snacks and/or finger foods

The 2022 ESPEN practical guidelines on clinical nutrition and hydration in geriatrics (10) recommend that older adults who are at either nutritional risk or are malnourished should be provided with fortified snacks and/or finger foods to ensure that their protein and energy needs are met. This recommendation is based on the following studies:

- Bunn et al. published a systematic review in 2016 that looked at interventions that could indirectly affect the dietary and liquid intake in people with dementia (112). That review included 51 studies of which five included snacks and/or finger foods as part of their intervention (113-117). The snacks and/or finger foods were never the sole intervention, making it difficult to conclude whether their inclusion affected the outcomes.
- Abdelhamid et al. carried out a systematic review and meta-analysis to determine what elements of nutritional interventions would directly

support the sufficient intake of both food and drink in people with dementia (118). Among the 43 included reports, six studies provided snacks and/or finger foods to the participants (113, 116, 119-122). The authors concluded that the interventions had no noticeable effects (neither positive nor negative), but highlighted that the studies had few participants and the interventions were implemented for a short time (118). Some of the interventions that showed a tendency towards positive effects provided finger foods (118).

- Two systematic reviews that also serve as the basis for the fortification of foods in the ESPEN recommendation are authored by Morilla-Herrera et al. (98) and Trabal et al. (97). The studies that included snacks and/or finger foods in the abovementioned systematic reviews are part of bigger interventions, where the effects of snacks and/or finger foods was not the only component being assessed.

ESPEN concluded that, although the evidence is inconclusive and there is still a need for large-scale RCTs on the subject, there is no harm in recommending the provision of snacks and/or finger foods and also their cost is low (10).

To determine whether more recent findings on the fortification or energy enrichment of snacks and/or finger foods for malnourished or nutritionally at-risk older adults were available to support the recommendation in the ESPEN guideline, we conducted an extensive search to find reviews, meta-analyses and/or RCTs from 2016 to the present day because the search for the recommendation in the ESPEN guideline was conducted pre-2017. The following reports were found:

- An RCT by Nykänen et al. on older adults receiving home care included $N = 85$ participants, with $n = 50$ in the intervention group and $n = 35$ in the control group (123). The intervention group was provided with high-protein dairy-based and energy-enriched berry snacks providing approximately 300 kcal/day and 14 g protein/day to determine whether it could positively affect their nutritional status and physical function (123). The nutritional status, albumin and handgrip strength significantly improved in the intervention group, whereas albumin and handgrip strength declined in the control group (123).
- In a 2017 RCT, either a protein- or an energy-rich bar or gel was added to the diet of older women on three separate occasions around breakfast time. As a result, their overall intake increased and their appetite was not affected (124). The bar and gel were enriched with essential amino acids, instead of protein, to minimise the effect on appetite as a decline in appetite is a well-known causal factor affecting the decreased dietary intake of older adults (124).
- The systematic review and meta-analysis by Sossen et al., mentioned in Chapter 2.3.2.1 concluded that the supply of not only fortified food but

also fortified snacks positively affects nutritional intake, but mentioned that more studies on these effects are needed (104).

To increase the appeal of the food and snacks we provided, an important factor of our intervention was that we both asked older adults in a nursing home which foods and snacks they preferred, and we conducted a sensory test that involved both older adults and a sensory panel to adjust the foods and snacks to their liking. The personal preferences of those receiving nutritional interventions have been studied, and we found that:

- In 2021, Wendin et al. sought to find out what older adults want in the in-between-meals snacks they consume (125). These authors found that these consumers preferred colourful and small energy- and protein-enriched snacks. An appropriate serving temperature was the most influential factor related to the taste, texture and flavour of the snacks (125).
- Ingadottir et al. carried out a feasibility study on COPD patients in Iceland, following them from admission to the hospital and for 12 months afterwards (126). These authors wanted to elucidate whether freely provided ONS vs protein- and energy-rich snacks had any effects on body weight, body composition and HRQoL (126). They found improvements for all outcomes but the group that received the snacks maintained its HRQoL improvement at 12 months, whereas the HRQoL scores of the ONS group started to decline as the intervention progressed, indicating an increased liking and/or adherence to the snacks provided (126).

The abovementioned studies and reviews on the fortification of foods, snacks and/or finger foods are important. However, knowledge is still lacking about the effects of fortification, not only on the protein and energy intake but also on the nutritional status and other relevant outcomes of the older adults when they receive free protein- and energy-rich foods and snacks for six months.

2.3.2.3 Oral Nutritional Supplements (ONS)

The ESPEN guideline for geriatrics for older adults recommends the addition of ONS when the NT and fortification of food and snacks have been implemented without satisfactory results (10). The addition of ONS is recommended in different settings, such as:

For older adults affected by a chronic condition or conditions and either at nutritional risk or malnourished, ONS should be used in addition to fortified foods, snacks and NT to increase energy and protein intake regardless of setting (10). This recommendation is based on four RCTs because no systematic review that compared ONS to either fortification of foods and

snacks or NT was available at the time when the ESPEN guidelines were published (literary search pre-2017) (10). The included RCTs for this recommendation are:

- An RCT by Gray-Donald et al., where 50 frail community-dwelling older adults (> 60 years old) were randomised into either a group receiving ONS from a dietitian or a group receiving visits from a dietitian providing NT (127). The intervention group gained more weight than the control group (2.1 +/- 2.3 vs. 0.6 +/- 1.6 kg; $P < 0.01$) after the 12-week trial period, but no difference was found in functional measures except for a slight decrease in falls in the intervention group (127).
- An RCT involving 58 participants at nutritional risk in a long-term care facility. The control group received the usual diet + three snacks between meals and the intervention group received the usual diet + three ONS between meals (128). Both groups significantly increased their energy intake; the snack group by 30% and the ONS group by 50% compared to their baseline intake (128).
- A 12-week RCT where the participants (residents in a long-term care facility) were at moderate or high risk of malnutrition (129). The control group (n = 51) received dietary advice and the intervention group (n = 53) received ONS, resulting in significant improvements in HRQoL and energy and protein intake in the intervention group (129).
- A double-blind RCT where the intervention group (n = 313) received ONS and the control group (n = 309) received a placebo for 90 days post-discharge from the hospital. This resulted in a lower mortality rate at 90 days in the intervention group and improved nutritional status (130).

Older hospitalised adults who have been identified as being malnourished or are at risk of being malnourished should be provided with ONS to increase both body weight and nutritional intake and decrease complications and readmission rates (10). This recommendation is based on studies showing significant improvements in different outcomes (e.g., an improvement in both body weight and nutritional intake (131-134), reduction of complications (134) and fewer readmissions (131, 134, 135)). However, statistically significant results were not found regarding improvements in outcomes such as the reduction in mortality (131-134, 136) and LOS (131, 134, 136), and contradictory results were found regarding physical function (133, 134).

When an older adult, who is assessed as being at risk of malnutrition or malnourished during hospitalisation, is discharged from the hospital, they should be advised to supplement their diet with ONS to improve protein and energy intake and increase body weight, while also reducing the risk of functional decline (10). This is recommended based on the following studies:

- A systematic review focusing on the post-discharge period in older adults found that ONS improves nutritional intake and body weight but has no effect on the risk of readmission or mortality (132). The review included six trials of which two showed positive functional effects, one on handgrip strength (137) and the other one on ADL (138).
- An RCT providing a combination of NT and ONS to their intervention group (n = 29) for four months post-hospital discharge (85). The intervention received two NT sessions by a dietitian + three phone calls and ONS (1–2 daily), resulting in positive effects on body weight and ADL compared to the control group (n = 25) (85).
- An RCT showing a positive effect on ADL, where the intervention group (n = 105) received NT, NT via telephone, a protein- and energy-enriched diet, ONS and a calcium-vitamin D supplement for three months post-discharge vs the control group (n = 105) that received the usual care (91, 139).

ESPEN further recommends that, whenever ONS is implemented, it should:

- Provide ≥ 400 kcal/day and ≥ 30 g protein/day. This recommendation is based on the following studies:
    - A large systematic review encompassed 62 RCTs, where subgroup analyses consistently yielded statistically significant results on mortality when focusing on trials where ONS provided a minimum of 400 kcal/day (133).
    - A systematic literary review that specifically examined high-protein ONS, and observed and reported various effects across different settings and patient groups (134). The authors reported an increased protein and energy intake without reducing the intake of conventional food, a decreased risk of readmissions and complications and an improvement in handgrip strength and body weight (134). The high-protein ONS, comprised more than 400 kcal/day in 16 trials and had an average protein content of 29% (ranging from 20% to 40%).
- ONS should be provided for at least a month and its effects on body weight and nutritional status should be assessed at least monthly. Malnourished older adults have a harder time gaining weight compared to their younger counterparts; thus, any nutritional intervention should last for a minimum of one month to improve nutritional status along with other clinically relevant outcomes (140). This recommendation is based on the following systematic review:

  - Milne et al., where both their subgroup analysis in 2002 (141) and 2005 (142) revealed significant effects on mortality when using ONS for ≥ 35 days in comparison to < 35 days. However, in the Milne et al. update in 2009, ONS no longer positively affected mortality (133). In the 2009 update, the ONS was not always used for ≥ 35 days, which may have affected the outcome (133).

- Compliance with ONS should be assessed regularly and special care should be taken to find the most appropriate type of ONS when it comes to flavour, time of consumption and texture that is adequate for the older adult (10). Moreover, their ability to eat should also be considered (10). This recommendation is based on the following study:

  - A systematic review by Hubbard et al. on compliance with ONS, where most participants in the included trials were older adults (mean age of 74 years) within various settings. The authors found good compliance with ONS (143). Compliance was 67% in the hospital, whereas, it was 81% in the community, resulting in an overall compliance of 78%. Factors negatively influencing compliance were more advanced age and the energy richness of the ONS consumed. A minimal change in usual food consumption was observed despite the addition of ONS, which resulted in higher energy intake in the intervention group (143).

The ESPEN recommendations for ONS rely on studies published before 2016. A few systematic reviews and meta-analyses have been published recently, with different research questions:

- A 2021 systematic review and meta-analysis on RCTs by Li et al. evaluated the effectiveness of ONS on older adults affected by anorexia of ageing (144). The authors found that ONS significantly improved appetite, energy, fat and protein intake, body weight and BMI in those taking ONS (144).
- In 2022 Thomson et al. published a systematic review and meta-analysis where they looked into what, if any, effects ONS has on frail older adults at risk of malnutrition or malnourished, based on eleven RCTs (six partially or completely funded by the industry) (15). The authors also wanted to determine whether the addition of ONS would be cost-effective and found one study that evaluated the cost-effectiveness of ONS in a nursing home (145). They found that the addition of ONS resulted in a slight increase in protein and energy intake and mobility (15). No clear results were found for HRQoL. Moreover, the authors

concluded that ONS could possibly be cost-effective but further research is needed regarding these outcomes, and trials not funded by the industry and with sufficient statistical power and adequate length of intervention are required (15).

- Lester et al. performed a review of the literature to find out which factors are most important to the adherence to ONS in older adults (146). Adherence to ONS is crucial to attain meaningful outcomes. These authors found that the factors affecting adherence could be categorised into three areas:
    - Environmental factors: healthcare staff, social aspects and correct timing. Thus, they recommended teaching any caretakers, formal or informal, about ONS.
    - Personal factors: views and drives, consumption behaviour, age, sensory decline and familiarity. To improve personal factors, the authors recommended that ONS should be presented to the person receiving it according to their liking and abilities and they should be provided with the appropriate tools to be able to consume the ONS.
    - Product factors: ONS type and preference, volume and energy density, thickness, trigeminal stimuli (pungent sensation), tastants (sweet, sour, bitter, salty or umami/savoury), viscosity and aroma. To improve these factors, the authors recommend that the texture and flavour of the ONS should be specially designed for older adults (146).
- Cawood et al. carried out a systematic review and meta-analysis of the effects of ONS on clinical outcomes within the community (147). Persons ≥ 18 years of age with a mean age of 67 years were included in the 44 RCTs considered for the review. The results showed that providing nutritionally at-risk adults with ONS reduced complications (e.g., fewer infections and pressure ulcers, and wound and fracture healing significantly increased by 30%). This was true for both the time when the intervention started in the hospital and afterwards in the community setting. The RCTs that showed a decrease in complications provided liquid ONS and had a high adherence to it (≥ 80%). In the meta-analysis on adults ≥ 65 years, the reduction of complications was also statistically significant (134).

Despite the abovementioned recent reviews, the heterogeneity of the included RCTs is substantial when it comes to both settings and interventions. There is still a knowledge gap regarding the implementation of ONS to older adults at nutritional risk, who are also receiving NT and protein- and energy-fortified foods and snacks to improve their physical and psychological factors after hospital discharge.

2.3.2.4 Meals on Wheels (MOW)

MOW is a service where people can order cooked meals and have them sent to their homes. In Iceland, it is possible to have one meal a day delivered for lunch; however, the meal is not especially protein- and/or energy-enriched. The idea of MOW is to provide people who may be unable to cook proper meals for themselves with a homecooked meal to help them reach their nutritional needs. For older community-dwelling adults incapable of shopping for groceries or preparing meals, having access to ready meals at home is crucial to be able to maintain independence (10). Whenever older community-dwelling adults at nutritional risk or malnourished receive MOW, the meal provided should be energy-rich and/or include more than one meal or snack a day (10). This is according to the ESPEN practical guidelines on clinical nutrition and hydration in geriatrics to ensure that the nutritional needs of the MOW recipient are met (10). This recommendation is based on the following studies:

- A literary review by Sahyoun and Vaudin (148), where they sought to find possible positive effects of receiving MOW. They found that MOW increased energy intake and that this increase was proportional to how many meals were provided (i.e., more meals = better results), particularly when the beneficiaries were those at most nutritional risk (148). Sahyoun and Vaudin also highlighted that, if only one meal a day is provided to individuals incapable of grocery shopping and/or unable to prepare and cook meals, and/or who do not have a solid social network to get help from, it could lead to a decrease in intake as this one MOW meal would be all they consume on that day, which would not be sufficient to fulfil their nutritional needs (148).
- A randomised within-participants crossover trial by Silver et al. (149) showed that by energy-enriching MOW, mainly with fat, a significantly higher calorie and nutrient intake was attained both during the meal and at 24 hours, estimated by taking a 24-hour dietary recall (24HR). They concluded that the effectiveness of energy-enriching MOW seems to be appropriate to increase intake and probably the recipient's nutritional status.
- Kretser et al. (150) conducted a six-month RCT where the intervention group received MOW that included three meals and two snacks a day for seven days a week, providing them with 100% of their recommended daily intake. The control group received traditional MOW that included one meal a day, providing a third of their recommended daily intake for five days a week. A significant increase in body weight was found at both three and six months in the intervention group, and the nutritional

status of this group improved more quickly than that of the control group (150).

The abovementioned studies show the importance of taking into consideration the nutritional needs of the recipients of MOW and that, with changes to the ratio of macronutrients, a considerable enrichment can be achieved with positive outcomes.

More recent findings support this ESPEN recommendation:

- Walton et al. published a systematic literary review in 2019 (151), which looked at whether community-dwelling older adults receiving MOW would increase their dietary intake in comparison to those not receiving MOW. Thirteen studies were included in their analysis, with results showing that MOW increased protein, energy and micronutrient intake (151).
- In their review, Ijmker-Hemink et al. sought to find out which elements of MOW allow it to increase the protein and energy intake of its recipients, thus improving crucial outcomes (14). Nineteen studies met their criteria and were included in their systematic review. They found that, for MOW to improve outcomes such as protein and energy intake, more than one meal per day should be provided (14). They concluded that to be able to decide anything on outcomes such as improved nutritional status and function, more well-designed RCTs using standardised methods are needed (14). In conclusion, these authors suggest that MOW services should focus on their recipients and tailor the food to their needs. For older adults unable to go shopping or cook for themselves, it is crucial to have good-tasting food that is to their liking, providing smaller energy-rich portions, having convenient packaging and offering a variety of meal options (14).
- The nutritional problems of older adults receiving MOW were investigated by Fleury et al. in a systematic review (152). These authors noted that a high proportion of MOW recipients are at nutritional risk or are malnourished (15 studies > 35%, 10 studies > 70%), making them a vulnerable population. MOW may have positive effects on protein, energy and nutrient intake, which can be further improved if other components are added to the MOW service (e.g., NT, enrichment of foods and/or snacks and/or the addition of more meals/snacks than the one a day usually provided) (152).

Even though recent systematic reviews show the positive impact of providing MOW, there is still a lack of knowledge about the effects MOW would have in conjunction with several other aspects that allow the recipients to fully meet their nutritional needs. If considering MOW alone, more studies on providing

energy- and protein-enriched meals and snacks to older adults at nutritional risk for a long time (more than a few weeks) are needed to obtain more clinically relevant outcomes. This is especially true for those discharged from the hospital because hospital stays are short, leaving little time to correct malnutrition.

3 Aims

The aim of the present doctoral dissertation was to investigate the effects of NT using the NCP and NCPT and providing free home-delivered protein- and energy-rich foods, snacks and ONS for six months to older adults at nutritional risk, who were discharged from hospital and lived independently thereafter. The assessed outcomes were the nutritional status, body weight, body composition, physical function, HRQoL, SRH, cognitive function, depression, hospital readmission, LOS, nursing home admission and mortality, in comparison to a control group that was discharged according to the current practice of Landspitali, The National University Hospital of Iceland.

Our specific aims were to:

1. Provide older adults with NT using the NCP and NCPT and managed by a dietitian, and also provide them with free protein- and energy-rich foods, and ONS/snacks for six months after discharge from hospital to independent living. We wanted to determine whether our intervention could prevent weight loss and muscle deterioration, and thus provide the participants with the best chances of maintaining or improving their physical function **(Paper I).**

2. Determine whether the provision of our nutritional intervention could not only improve the physical aspects of older adults but also improve their HRQoL, depressive symptoms, SRH and cognitive function **(Paper II).**

3. Find out whether the provided intervention would reduce ER visits and hospital readmissions, shorten LOS and decrease mortality during the intervention phase and at one, six, twelve and 18 months, even though the intervention was only provided for six months **(Paper III).**

4 Materials and methods

For a more thorough description of the materials and methods, see **Papers I, II and III**.

4.1 Study design

The HOMEFOOD study was a randomised controlled intervention trial, with blinded trial assessors and an intervention period lasting for six months after hospital discharge. Participants were nutritionally at-risk community-dwelling older adults (≥ 65 years), living in or around Reykjavik, Iceland. The first participant received the intervention in January 2019 and the last participant received the intervention in July 2020. The outcomes reported in the papers this dissertation is based on are summarised in Table 2.

Table 2 – Outcomes

	Paper I	**Paper II**	**Paper III**
Main outcomes	Body weight changes and physical function	HRQoL, SRH, cognitive function and depressive symptoms	Hospital readmissions, Nursing home pre-admission assessments (NHPAA), ER visits and LOS
Other outcomes	Body composition, muscle strength, dietary intake, nutritional risk and food-related adverse events	Body weight, dietary intake and food-related adverse events	Nutritional risk, dietary intake, body weight, physical function, cognitive function, depressive symptoms and food-related adverse events

4.2 Reporting, approval and funding

The Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomised trials of nonpharmacologic treatments were applied for conducting and reporting this trial (153). The study received approval from the Ethics Committee for Health Research of Landspitali, the National University Hospital of Iceland, and the data protection registry (24/2018) in August 2018. The ethical standards laid down in the 1964 Declaration of Helsinki were followed in the conduction of the study (154). The study was registered and is available at clinicaltrials.gov (NCT03995303). Foods, snacks and ONS were kindly developed, produced and provided by Icelandic food companies (Sláturfélag Suðurlands Ltd., Grimur Kokkur Ltd. and MS Iceland Dairies). The companies delivered the foods and ONS to a facility in Reykjavik, where members of the research team divided and delivered the food, snacks and ONS packages to the participants. Funding was kindly provided by the Icelandic Research Fund (174250-051), the Research Fund of Hrafnista, the Gerontological Association of Iceland, the Research Fund of the University of Iceland and the Helga Jonsdottir and Sigurlidi Kristjansson Geriatric Research Fund. Grants were provided without any conditions. Neither the funding entities nor the food companies were involved in the study design, execution, statistical analysis or writing of the scientific papers.

4.3 Development of protein- and energy-rich foods, snacks and ONS

In the preparation phase of the HOMEFOOD study, the foods offered to the participants in the intervention group had to be developed. As part of this study, an MSc student in food science at the University of Iceland, Erna Dögg Úlfhéðinsdóttir, developed energy- and protein-rich foods, snacks and ONS that were both tasty and flavourful for older adults in Iceland, in cooperation with the food companies mentioned earlier. All produced food, snacks and ONS were sensory analysed by multimorbid older adults in geriatric rehabilitation at Landakot University Hospital (155). Three food companies in Iceland (Mjólkursamsalan, Grímur Kokkur, and Sláturfélag Suðurlands) developed the ONS, foods and snacks with instructions regarding the components to be included given by the author of this dissertation (Berglind S. Á. Blöndal) and her supervisors, Alfons Ramel and Ólöf Guðný Geirsdóttir, who are dietitians and experts in the nutrition of older adults.

Important factors considered in the development of the food products were:

- Increased protein needs of older adults.
- Decreased appetite of nutritionally at-risk older adults; thus, energy-rich foods and snacks (including ONS) were required to provide more energy in each bite or sip.

- Soft texture to prevent chewing or swallowing difficulties.
- Ease of opening packages, in case of reduced mobility and/or muscular strength.
- Preferences of older adults—interviews were conducted in that age group to evaluate their habits and preferences regarding favourite meals.

Grímur Kokkur, a fish company, and Sláturfélag Suðurlands, a meat company, developed eight different traditional meals, and Mjólkursamsalan developed an ONS with two flavour options as well as four types of protein- and energy-rich snacks. The finished products were then sensory tested, improved and then further tested by older adults at K1, a geriatric day ward at the hospital, to ensure that the foods were suitable for the study population regarding taste, smell, texture and ease of consumption. Pictures of some of the foods and ONS developed for the study are displayed in Figure 4.

Figure 4 - Traditional Icelandic foods and ONS created for the intervention group.

4.4 Screening and recruitment

The participants were older adults (≥ 65 years) discharged home to independent living from two geriatric wards (L2 and B4) and one medical ward (A2) at Landspitali, the National University Hospital of Iceland, that met the study's inclusion and exclusion criteria (Table 3). During the recruitment process, all patients of the two geriatric wards and the medical ward were pre-screened by a dietitian and members of the research team to determine whether they met the inclusion criteria of the study. Recruitment took place in the period from January 2019 to January 2020, with the intervention being delivered from January 2019 to July 2020.

Table 3 - Inclusion and exclusion criteria

Inclusion criteria	**Exclusion criteria**
≥ 65 years old	MMSE[1] ≤ 20 within the past 3 months
Community-dwelling in the capital area	Known dietary allergies
At nutritional risk (ISNST[2] ≥ 3) according to the validated ISNST	Being on a special diet
Given informed written consent	Severe chronic kidney disease (GFR[3] < 30 mL/min/1.73 m^2)
Discharging home in the capital area	Admission to a nursing home or other wards
Have a functioning kitchen at home	In active cancer treatment
Living in the Reykjavík capital area	Relying on tubal feeding
Able to understand and communicate with the research team	Declining participation

[1]MMSE = Mini-Mental State Examination, scoring from 0 to 30, where 0–17: severe impairment, 18–24: mild impairment, and 24–30: no impairment.
[2]ISNST = Icelandic Nutrition Screening Tool; score range: 1–30, 1–2 = low nutritional risk, 3–4 = some nutritional risk, ≥ 5 = high nutritional risk.
[3]GFR = Glomerular filtration rate, where < 30 represents severely decreased kidney function and < 15 represents kidney failure.

Further information on the screening and recruitment process is presented in Figure 1 of **Paper I**.

The randomisation process is listed in Table 4.

Table 4 – Randomisation

Allocation ratio	A ratio of 1:1 to either the intervention or control group.
Generation of random numbers for allocation	The Statistical Package for the Social Sciences (SPSS), version 26.0, SPSS, Chicago, IL, USA; conducted with the random number generator.
Blinding	Allocation was blinded and provided by the principal investigator at the time of assignment of each participant, thus ensuring blinding of the dietitian who recruited participants until the time of assignment.
Endpoint measure	Taken by investigators who were blinded to the intervention and had not taken part in any of the study´s aspects, and were thus blinded to which group the participant was in. A questionnaire and 24HR were the last part of the assessment and revealed at the end of it which group the participant was in.

4.5 Intervention group

The intervention is described in detail in **Papers I, II and III**. A summary of the components included in the intervention is shown in Figure 5.

On the first visit, the Icelandic guidelines for frail or sick older adults were printed and given and explained to the participants and their caregivers (156).

- On Day one after discharge and at Weeks one, three, six and twelve: the dietitian visited the participant at home and invited the caregivers (formal and informal) to take part in the intervention. The dietitian provided the participant with NT using the NCP and NCPT (94) and set up nutritional goals according to the participant's individual needs. The NCP provides the dietitian with a methodical way to assess, diagnose, intervene, monitor and evaluate (and, at later visits, re-evaluate) the NT given.

- At each visit from the dietitian (Day one, and Weeks three, six and twelve), the participant was assessed, including:
    - Collection of information on dietary intake, diseases, gastrointestinal problems, biochemical data, anthropometric measures (body weight), adherence to the protein- and energy-enriched foods, snacks and ONS, and any adverse events from the intervention foods, snacks and ONS.
    - A nutritional diagnosis was made, where the dietitian selected the nutritional intervention most appropriate to tackle the cause/s of the nutritional problem/s of the participant, with the specific aim to relieve the participant of their nutritional symptoms. Follow-up was planned and the dietitian monitored and evaluated whether the implemented intervention had delivered the intended results. This last step would lead to either the resolution of the problem or a new nutritional diagnosis to work towards solving.
- As part of the NT, participants received phone calls from the dietitian to encourage adherence to the intervention and to answer any questions that may have come up at Weeks two, five and nine where the participants were also asked if they were experiencing any adverse events if they adhered to the intervention and if any problems arose and were solved.
- On Days one or two and weekly thereafter for 24 weeks, the participants received food, snacks and ONS from members of the research team.
- At each delivery, the researcher who delivered foods, snacks and ONS provided instructions for keeping and cooking the foods provided; the participant's refrigerator was cleared of foods that were past the best-by date, a record was made of which foods were left over and which foods each participant preferred for the next delivery, and foods, snacks and ONS were placed in the refrigerator.

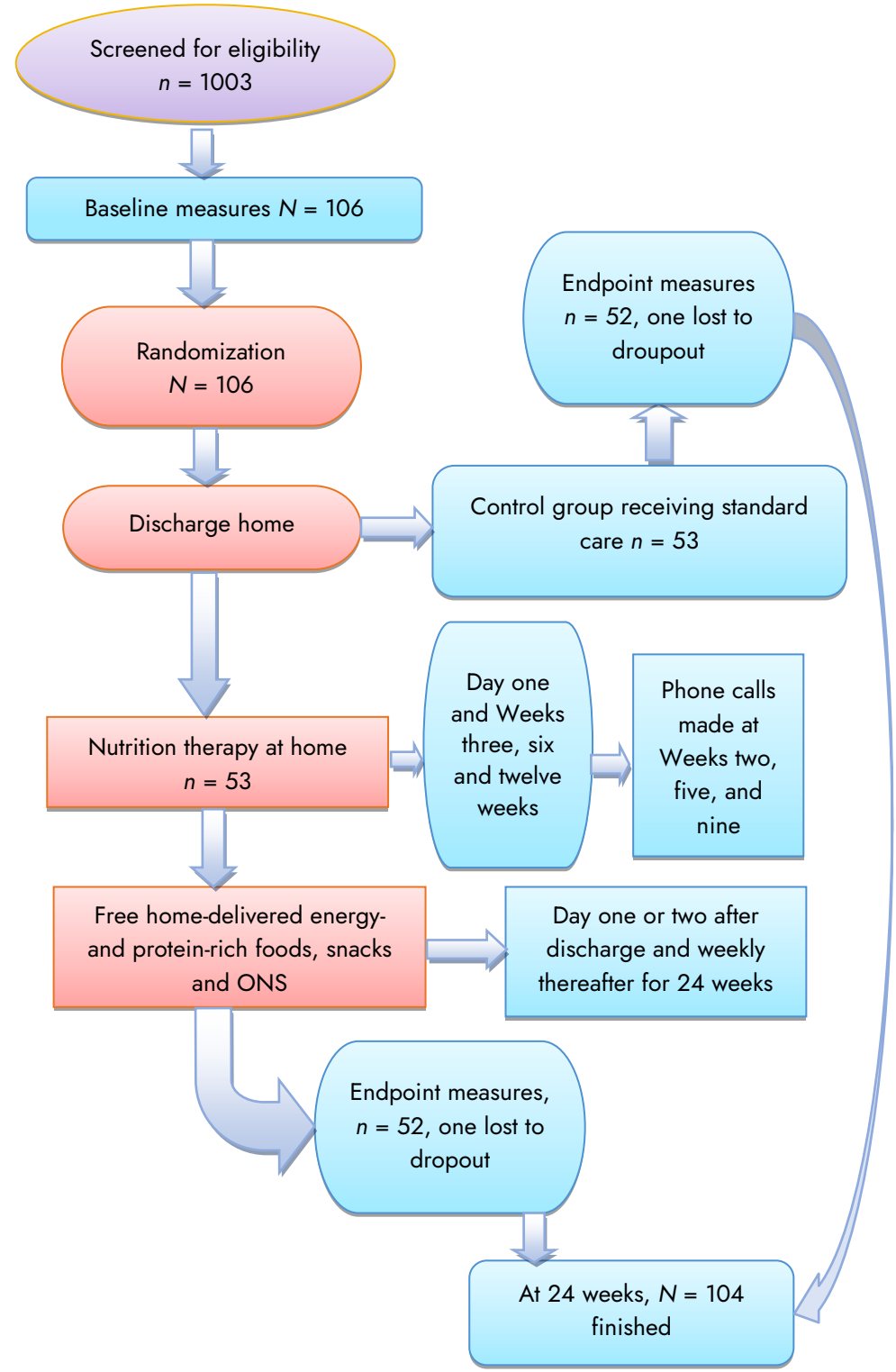

Figure 5 - Components of the intervention

4.6 Control group

The control group is described in detail in **Papers I, II and III**. A summary of the components included in the control group are:

At discharge:

- The control group received the current standard of care, which includes:
  - Information on the nutrition of older sick and/or frail adults, provided to the older adults and their caregivers and sourced from the Directorate of Health (156).
  - Participants were advised to order MOW.

4.7 Participant baseline and outcome measures

A description of the participants' baseline and outcome measures is provided in detail in **Papers I, II and III**. A summary of the outcomes assessed is provided in this chapter. The overall enrolment, allocation, post-allocation, close-out and assessments made at each study period are shown in Table 5, which is the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) chart. Additionally, Table 5 shows which components were measured by the study´s dietitian at each visit and phone call to the participants in the intervention group.

Table 5 - Overview of baseline measures and how they were obtained

	STUDY PERIOD					
	Enrolment	**Allocation**	**Post-allocation**		**Close-out**	
TIMEPOINT	t_{-1}	t_0	$t_{+30\ days}$	$t_{+180\ days}$	$t_{+12\ months}$	$t_{+18\ months}$
ENROLMENT						
Eligibility screening	X					
Informed consent	X					
Baseline measures	X					
Allocation		X				
INTERVEN-TIONS:	**Enrolment**	**Allocation**	**Post-allocation**		**Close-out**	
Intervention group			←	—	—	→
Control group						

ASSESSMENT	Enrolment	Allocation	Post-allocation	Close-out
Baseline characteristics*: sex, age, smoking, alcohol consumption, marital status, blood pressure, height, weight, BMI[1], nutritional risk, MMSE[2], diagnosis, bloodwork		X		
Outcome variables: Anthropometrics, physical function, muscular strength, dietary intake, nutritional status, HRQoL[3], SRH[4], MMSE[2], CES-D[5]	X		X	X
Outcome variables*: LOS[6], (re-) admissions, ER[7] visits, NHPAA[8], mortality			X	X

ASSESSMENT	Enrolment	Allocation	Post-allocation	Close-out
Outcome variables specific to the intervention group:** Anthropometrics, dietary intake, nutritional status, food-related adverse events to intervention food, ONS[9] and snacks			X	X

***** Information obtained from the Icelandic electronic hospital registry, SAGA (TM software 3.1.39.9).
****** Taken at each visit by the dietitian on Day one and Weeks three, six and twelve adverse events were also recorded during each follow-up phone call at Weeks two, five and nine
[1]**BMI:** Body mass index, kg/m^2.
[2]**MMSE:** Mini-Mental State Examination; scores from 0 to 30, where 0–17: severe impairment, 18–24: mild impairment, 24–30: no impairment.
[3]**HRQoL:** Health-related quality of life, measured with EQ5D = EuroQol five-dimension (EQ-5D) quality of life index, ranging from -0.624 to 1.0, covering from very poor health-related quality of life (HRQoL) to perfect HRQoL.
[4]**SRH:** Self-rated health; the EQ-5D instrument contains a visual analogue scale (VAS) by which participants self-rate their health from 0 (worst health possible) to 100 (best health possible).
[5]**CES-D:** Centre for Epidemiologic Studies Depression Scale IOWA variant; score range 0–22, > 9 = presence of depressive symptoms.
[6]**LOS:** Length of hospital stay
[7]**ER:** Emergency room.
[9]**NHPAA:** Nursing home pre-admission assessment.
[9]**ONS:** Oral nutritional supplements.

4.8 Outcomes

4.8.1 Nutritional risk

According to the Icelandic Medical Directorate of Health, it is recommended to assess older adults for nutritional risk, using the validated ISNST (156, 157). Their guidelines are that older adults should be screened yearly within any healthcare setting, on admission to the hospital and weekly whilst admitted to the hospital if a low nutritional risk is present. Other guidelines are provided for those at moderate and high nutritional risk (see Chapter 2.2.5 for a detailed description of the recommendations). The ISNST was used in this study and Table 1 summarises the measures and scores it uses to assess nutritional risk.

4.8.2 Dietary intake

The energy and protein needs of each participant were calculated according to ESPEN´s recommendations for the energy (30 kcal/kg body weight/day) and protein (1.0–2.0 g/kg body weight/day) intake for older adults (10). The calculations were adjusted to the category of normal weight according to the BMI (23–29.9 (158)). Recordings of the participants' dietary consumption were assessed using the 24HR method at the baseline and at six months. Dietitians are trained to methodically obtain information on all foods and drinks consumed within a 24-hour period, from midnight to midnight, using the 24HR (159). Although it has been reported that older community-dwelling adults who do not meet their nutritional needs overreport their intake in the 24HR method and those who intake more than their energy needs underreport it, this method is considered the most accurate way to measure the participants' energy and protein intake (160). After the two 24HR of the participants had been entered into Excel, the data was input into ICEFOOD, a nutrition calculator that estimates the energy and protein intake for the food entered (161, 162). ICEFOOD is based on ISGEM, an Icelandic database of Icelandic foods and recipes that has been used to estimate what Icelanders eat, based on surveys conducted in 2002, 2011 and 2021 (161, 162). The foods, snacks and ONS used in the HOMEFOOD study were input into the ICEFOOD database.

The dietary intake of the participants in the control group was assessed using the 24HR at each home visit/phone call from the dietitian. The goal was not only to assess the dietary intake but also to assess whether compliance with the foods, snacks and ONS was sufficient or if any adjustments were needed. The serving sizes were assessed in the home of the participant, where the dietitian would ask them to show which bowl, glass or plate was used, how much was put on/in the bowl, glass or plate, and how much was consumed from it.

To assess the frequency of specific dietary behaviours, such as the frequency of hot meals and consumption of protein-rich foods, dairy, fruits and vegetables, a food frequency questionnaire was used (163).

4.8.2.1 Adverse digestive events

As part of the NT and NCP, adverse events on digestion-related issues were noted; these could be nausea, stomach-ache, diarrhoea or constipation. The ISNST includes questions regarding digestive issues (e.g., low appetite, chronic diarrhoea and vomiting), which were also used to assess which components might be possible contributors to the nutritional risk or increased need for fluids.

4.8.3 Anthropometrics

Table 7 lists anthropometrics along with the measuring devices used, the settings and timepoints. For a more detailed listing of the anthropometric measures, see the methodology in **Papers I, II and III**.

Table 6 - Anthropometrics

Anthropometrics				
Measure	**Situation**	**Measuring device**	**Base-line**	**End-point**
Body weight	Light clothing/ underwear	708 Seca body weight scale	X	X
Height	Standing	SAGA hospital registry*	X	
BMI**		Calculation, kg/m^2	X	X
Body composition	Standing with arms straight out in front of the body at a 90° angle, light clothing or underwear, fasting state for at least two hours (both food and drinks), no strenuous exercise 24 hours prior.	BIA***, Omron HBF-306C	X	X
Calf circum-ference	Sitting, oedema was assessed by the evaluator with the pitting technique.	Measuring tape	X	X
Mid-arm circum-ference	Sitting	Measuring tape	X	X
Waist circum-ference	Standing	Measuring tape	X	X

*SAGA = The Icelandic electronic hospital registry.

**BMI = Body mass index.

***BIA = Bio-electrical impedance analysis.

4.8.4 Physical function and muscular strength

4.8.4.1 Physical function

The components of the Short Physical Performance Battery (SPPB) test are listed in Table 8 (164). The SPPB was used to measure physical function with a question added about whether the participant had difficulties walking.

Table 7 - Physical function measured by the SPPB

Short Physical Performance Battery (SPPB)			
	Scenario	**Measure**	**Points**
Gait speed **Not used for practical reasons**	4 m course	Seconds	0–4
Standing balance			
Feet side by side	Standing	Able for 10 s	1
		Unable for 10 s	0
Feet in semi-tandem	Standing	Able for 10 s	1
		Unable for 10 s	0
Feet in tandem	Standing	Able for 10 s	2
		Able for 3–9.99 s	1
		Able for < 3 s	0
Repeated chair stands	Rises from the chair five times, without using arms		
Unable to within 60 s			0
Chair stand time 16.70 s or more			1
Chair stand time 13.70–16.69 s			2
Chair stand time 11.20–13.69 s			3
Chair stand time 11.19 s or less			4
The total available points for our shortened SPPB version were 0–8 points, where more points represent enhanced physical function			

4.8.4.2 Muscular strength

Handgrip strength was used to assess muscular strength and was measured using a hydraulic hand dynamometer, in a seated position, using the dominant hand. Measures were taken twice and registered in kilograms. For a more detailed listing of the physical function and muscular strength measures, see **Papers I, II and III**.

4.8.5 Cognitive function and health-related quality of life (HRQoL)

For a more detailed description of the methods used to assess cognitive function and HRQoL, see **Papers I, II and III**. A summary of the methods used for assessing cognitive function and HRQoL is listed in this chapter.

4.8.5.1 Cognitive function

The eleven-question questionnaire, MMSE, was used to assess whether the participants were cognitively impaired at the baseline and at six months (165). Repeated MMSEs at different timepoints were used to determine whether cognitive function had changed over time (21, 166). The scores of the MMSE are given in the range of 0–30 points, where:

- 0–17 points = severe cognitive impairment.
- 18–24 = mild cognitive impairment.
- 24 –30 = no cognitive impairment (21).

4.8.5.2 Health-related quality of life (HRQoL)

To assess the HRQoL of the participants the EuroQoL EQ-5D-5L questionnaire was used (registration No. 44069). The questionnaire asks questions about areas that have been shown to make a difference in terms of the ability to have a good quality of life; these areas are (167):

- Mobility: Difficulties experienced, if any, when walking.
- Self-care: Capability to wash and dress oneself.
- General activities: Ability to work, study, perform house chores, take care of the family, and be able to enjoy one's hobby/hobbies.
- Pain and/or discomfort: Whether one is suffering from pain or discomfort and to which level (none, some, considerable, a great deal, or enormous pain and/or discomfort).
- Anxiety and/or depression: Whether one is experiencing anxiety and/or depression (no symptoms, some, considerable, a great deal, or extreme symptoms of anxiety and/or depression).
- EQ-VAS: A visual analogue scale ranging from 0 to 100 that the participants place themselves in, where zero represents appalling health and 100 represents excellent health.

Scores from these areas were put into an index from the EQ-5D to observe where the participants placed themselves on the scale regarding their quality of life, ranging from very poor to a perfect HRQoL (167).

4.8.5.3 Self-rated health (SRH)

Self-rated health (SRH) uses a five-point Likert scale where participants rate their own perceived health ranging from 1 = excellent to 5 = poor. SRH is associated with both morbidity and mortality (19).

See **Paper II** for more details on HRQoL and SRH.

4.8.5.4 Depressive symptoms

The depressive symptoms of the participants were measured by the IOWA questionnaire, which is an 11-question variant of the CES-D (22, 168, 169). The questions asked about appetite, feelings (positive and negative), the ease of performing ADL, sleeping quality and their own perception of how others see them. The questionnaire can give a maximum of 22 points, where a score ≥ 9 indicates depressive symptoms.

4.8.6 Healthcare services and mortality

In the fall of 2021, the Icelandic electronic hospital registry, SAGA (TM software 3.1.39.9) was used to individually extract information on the following for each participant at one, six (end of the intervention), twelve and 18 months:

- Hospital readmissions: how many, within what timeframe of the study and the LOS counted in days.
- ER visits: how many and within what timeframe of the study.
- Whether the participant had undergone a nursing home pre-admission assessment (NHPAA). If yes, within what timeframe of the study? (Also, if yes, it would mean that the participant would not return home and would have to wait in the hospital for a nursing home placement).
- Mortality: if the participant had passed away. If yes, within what timeframe of the study?

Elective admissions to rehabilitation wards were not counted as readmissions because of their elective nature after a hospital stay, with a duration of one to three days per week, from 10:00 AM to 15:00 PM.

For greater details, see **Paper III**.

4.8.7 Sample size

The primary aim of our intervention was to try to positively affect the body weight of our target group (i.e., older adults being discharged to independent living). The focus on sample size calculations was centred on previous studies with body weight as an outcome (71, 170). Those studies showed that each

group needed 44 participants to show a statistically significant difference of 1.8 ± 3.0 kg body weight variation between them. To detect a statistically significant difference for an SPPB score of 1 with an assumed SD of 1.7, the groups needed 45 participants per group (171). As the recruitment process delivered > 50 participants in the two groups, it permitted a 10% dropout rate without losing the statistical power of the calculations on sample size.

4.8.8 Statistical analysis

SPSS, version 26.0, SPSS, Chicago, IL, USA, was used for data analysis. The Kolmogorov-Smirnov test was used to determine whether the data was normally distributed. The data were presented as mean ± standard deviation (SD). To detect differences between the intervention and the control group at the baseline, the independent samples *t*-test was used for normally distributed variables and the Mann-Whitney U-test was used for non-normally distributed variables. For categorical variables, a Chi-square test was used. An intention-to-treat analysis was also employed. Although randomisation was used, there was an unbalanced sex distribution in the groups; therefore, when analysing multivariate statistical endpoints, we corrected for sex. In the endpoint calculations, dropouts were included at the baseline, but not at the study endpoint. The significance level was set at $P < 0.05$. In **Paper I,** unadjusted analyses are shown in Supplementary Table 2 for comparison (172).

In **Paper I,** the continuous variables linear mixed models in SPSS were used to determine differences in the participants' anthropometrics and their physical outcomes, with results displayed as parameter estimates, where B represents the estimated and adjusted variations between the groups.

A logistic regression model was used to detect the differences in physical function between the groups at the endpoint, using the answers to SPPB and the lone question: 'Do you have difficulties walking?', where we corrected for matching baseline values and sex. Furthermore, a subgroup analysis was performed to determine changes in the weights of different matched groups, using the independent samples *t*-test (two-variable subgroup) or ANOVA with an LSD post-hoc test (three-variable subgroup). To observe the relationships among the subgroups and the intervention provided, we used a general linear model (see **Paper I** for further details).

In **Paper II,** to correct for sex in all outcomes, analyses of variance were used (173). To represent estimates of effect, we used means (β) with 95% confidence intervals (95% CI) to report our findings. Changes in outcome variables were compared against changes in body weight to determine whether they were linked by looking at the effect of the intervention in different body weight change quartiles. Differences were calculated using the general linear model univariate.

- Quartile one: Q1 = -6.4 ± 2.3 kg

- Quartile two: Q2 = -1.9 ± 1.2 kg
- Quartile three: Q3 = 0.4 ± 0.5 kg
- Quartile four: Q4 = 4.3 ± 2.2 kg

Contrasts were used to determine whether the differences followed a linear trend. See **Paper II** for further details.

In **Paper III,** the physical variables, mental health outcomes and dietary intake differences of the groups at the endpoint were examined using a general linear model, adjusting for baseline values and sex. The outcomes of continuous variables are represented as parameter estimates with 95% confidence intervals (95% CI), where the mean adjusted differences in outcome variables reflect the differences between the groups. To check for differences in hospital readmissions, ER visits, and LOS at one-, six-, twelve- and 18 months post-discharge from the hospital, a Mann-Whitney-U test was used.

For a percentage of those in both groups with at least one readmission and/or ER visit throughout the study period, a comparison was made with a sex-adjusted logistic regression analysis. Furthermore, to determine whether differences were detected in NHPAA and mortality between both groups, a sex-adjusted Cox regression analysis was performed. The time investigated covered from the start of the study (at hospital discharge when recruited and baseline measures were taken) until either dropout, death or 18 months after hospital discharge. The results are represented as hazard ratios. In **Paper III,** per-protocol analysis was used because it reflected that dropouts were included in the baseline and mortality analysis but excluded elsewhere. See **Paper III** for further details.

5 Results

This chapter presents the results of our three published papers. For more details, see **Papers I, II and III**.

5.1 Flow of the study

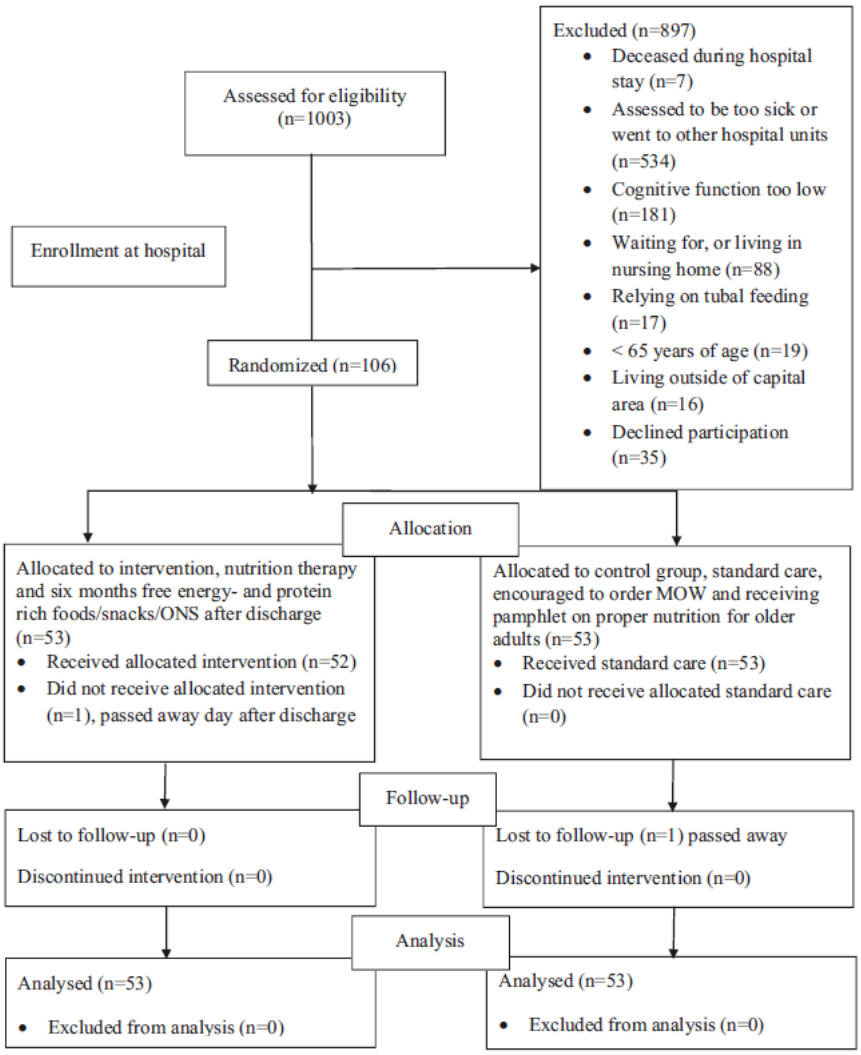

Figure 6 – CONSORT flowchart.

Flowchart of the assessment, recruitment, allocation, follow-up, and analysis process of the study (figure copied from **Papers I, II and III (172, 174, 175)**).

Figure 6 was copied with permission from **Papers I, II and III (172, 174, 175)**, and illustrates how the assessment, recruitment, allocation, follow-up, and analysis of the participants took place. We screened 1003 potential participants by going through all those admitted to the hospital wards where we had permission to recruit, to check for the eligibility of the patients. We consulted with the ward nurses about those deemed potential candidates for participation to find out whether they were well enough to participate. There were 897 individuals who did not meet our inclusion criteria; thus, 106 were recruited and signed an informed consent to participate. Background measures were taken, and then the participants were allocated randomly to either the intervention or the control group.

5.2 Dropouts

One participant dropped out of each group, leaving $n = 52$ in each group. The participant who dropped out of the intervention group passed away the day after discharge from the hospital and did not receive the allocated intervention. One participant in the control group passed away before the follow-up.
All but the dropout in the intervention group received five home visits from the study´s dietitian and three phone calls along with free delivered energy- and protein-rich foods, snacks and ONS (see Chapter 4.3 and Figure 4 for information on the foods, snacks and ONS; see Figure 5 for an illustration of the flow of the intervention).

5.3 Compliance

Compliance with the intervention was high. The NT was well received and both participants and their caregivers expressed that the NT was helpful and that they had learned useful facts to increase food intake. The protein- and energy-enriched food, snacks and ONS were all well received and none of the intervention participants disliked the food. The most liked foods were the fish meals (salted cod, fish stew, fish balls and fish burgers) from Grímur Kokkur and the lamb in bearnaise sauce, cabbage meat rolls and rice-liver pudding from Sláturfélag Suðurlands. The participants in the intervention group drank 1.7 ONS a day on average for the duration of the study (six months) and thoroughly liked the ONS, especially its creamy taste and consistency.

5.4 Adverse events

No adverse events or digestive discomfort related to the provided foods, snacks and ONS were reported by the participants in the intervention group.

Paper I

The primary outcome in terms of whether individual body weight changes would occur showed that the intervention group had a significant weight gain from the baseline to the endpoint (1.7 kg ± 2.5 kg, representing approximately a 2% increase in body weight). Nevertheless, one of the 53 individuals in the intervention group lost > 1 kg of body weight.

The control group had a significant weight loss from the baseline to the endpoint (−3.5 ± 3.9 kg, representing approximately a 5% loss of body weight, which is the amount of body weight lost associated with an increase in negative health outcomes like mortality) (176). Forty-two out of the 53 individuals in the control group lost > 1 kg of body weight. Upon accounting for sex differences, we observed that the intervention group had a body weight that was 5.1 kg (95% CI: 3.9, 6.4) higher than that of the control group at the endpoint measure. The adjusted variance in lean body mass amounted to 4.2 kg (95% CI: 2.7, 5.6).

A significant difference between the groups was found for BMI, and waist, midarm and calf circumferences, based on sex-adjusted values between the groups. Those in the intervention group with low BMI experienced the highest increase in body weight, whereas those in the middle BMI group remained pretty much at the same weight throughout the study period. In Supplementary Table 2 in **Paper I**, we presented all baseline and endpoint anthropometric measures without adjustment. As far as physical function is concerned, participants in the intervention group improved significantly in single physical performance tasks at the endpoint and performed better on several physical performance tasks (the adjusted results are shown in Table 4 in **Paper I** and the unadjusted results are shown in Supplementary Table 2 in **Paper I**) than the control. No statistical difference was detected in handgrip strength between the groups at the endpoint.

The control group had a worse nutritional status compared to the intervention group at the endpoint, measured with the ISNST. Although the baseline dietary intake of the two groups did not differ significantly (in the hospital), there was a significant increase in both energy and protein intake in the intervention group. On the other hand, we found a significant decrease in the protein and energy intake of the control group throughout the intervention period. The increase in dietary intake in the intervention group was significant (+937 ± 534 kcal/day, $P < 0.001$), whereas the control group had a reduction in dietary intake (-832 ± 407 kcal/day, $P < 0.001$) compared to the baseline dietary intake.

The ONS provided 24% of the total energy for the intervention group and 29% of the total protein consumed at the endpoint, representing a consumption of ≈ 1.75 ONS/day.

Most participants (>94%) in the intervention group reported that they liked the provided foods. Hot meals were consumed significantly more often in the intervention group than in the control group. The consumption of a daily hot meal was also more common in the intervention group than in the control group (96.2% vs 67.9%) at the endpoint (P = 0.003). Meat was consumed significantly more often in the intervention group at the endpoint (P = 0.007). The liquid intake of the intervention group was significantly improved (P = 0.014) at the endpoint and no digestive issues were reported in relation to the foods, snacks or ONS provided to the intervention group.

Based on robustness analyses, we determined that the effectiveness of the intervention remained unaffected by factors such as sex, marital status and the participants' age. By applying the NCP, we were able to provide a highly individualised intervention. Our goal was to achieve weight gain in the low BMI group, a smaller weight gain or weight stabilisation in the middle BMI group, and weight stabilisation in the high BMI group. To determine whether this was achieved, the variations in body weight among the different BMI categories were recorded. As a result, the interaction between BMI categories and the intervention was found to be statistically significant (P = 0.027).

Paper II

HRQoL significantly improved in the intervention group (P = 0.003), where HRQoL increased from 0.692 ± 0.147 at the baseline to 0.729 ± 0.131 at the endpoint. However, in the control group, the HRQoL decreased from 0.682 ± 0.190 at the baseline to 0.627 ± 0.225 at the endpoint. Here, a higher score means an improvement and a lower score means a decrease in HRQoL.

The visual analogue scale EQ-VAS is part of the EQ-5D and ranges from 0 to 100. Participants are asked to rate their health on the scale, with zero representing the worst health possible and 100 representing the best health possible. The SRH of the intervention group increased from 58.6 ± 20.1 at the baseline to 70.1 ± 17.4 at the endpoint; however, in the control group, it decreased from 61.2 ± 18.3 at the baseline to 54.0 ± 21.5 at the endpoint (P < 0.001).

The CES-D is a measure of depressive symptoms, where a score ≥ nine indicates such symptoms. Depressive symptoms increased in the control group from 5.6 ± 4.7 at the baseline to 8.0 ± 4.9 at the endpoint. By contrast, in the intervention group, the depressive symptoms decreased from 5.4 ± 4.2 at the baseline to 4.7 ± 3.2 at the endpoint (P < 0.001). These results produced

endpoint differences that were statistically significant between the groups (see adjusted results in Table 2 in **Paper II** and Appendix 3 in **Paper II,** which shows the unadjusted baseline and endpoint values of the outcome variables for each group).

At the endpoint, significant differences ($P < 0.05$) were observed in the MMSE, SRH and CES-D scores of the various weight-change categories. Additionally, during the intervention, changes in the primary outcome variables were linearly correlated with changes in body weight, namely MMSE ($P < 0.001$), SRH ($P < 0.001$) and CES-D ($P = 0.04$), except for EQ-5D (which measures HRQoL), where these associations were not significant.

Paper III

A shorter LOS (significant at all timepoints) and fewer readmissions (significant at one, six, and twelve months) were reported in the intervention group compared to the control group. Nevertheless, the number of ER visits did not differ significantly between the groups. Table 3 of **Paper III** shows the ER visits, readmissions, LOS and ratio of the participants with ≥ 1 readmission at one, six, twelve and 18 months after the first hospital discharge. Comparable findings were observed for participants who had had at least ≥ 1 hospital readmission in the study period.

Receiving a positive nursing home pre-admission assessment (NHPAA) while in the study and during the follow-up period was not significantly different between the groups (23.1% control vs 13.5% intervention) according to Cox regression analysis (intervention vs control group: HR = 0.54 (95% CI: 0.21–1.38, $P = 0.20$)).

Mortality did not differ significantly between the groups, with 9.4% passing away in each group while in the study and during the follow-up period, according to Cox regression analysis, adjusted for sex (intervention vs control group: HR = 0.97 (95% CI: 0.28–3.34, $P = 0.96$)).

5.5 Results from Papers I, II and III

Table 8 – Results from Paper I

		Control group (*n* = 53)				Intervention group (*n* = 53)				Between groups
Paper I - Main outcomes		**Mean**	**±**	**SD**	***P*-value**	**Mean**	**±**	**SD**	***P*-value**	***P*-value**
Body weight change (kg)	Baseline	76.5	±	19.1		78.3	±	18.3		0.511
	Endpoint	73.2	±	19.4	< 0.001	80.0	±	17.6	< 0.001	0.026
Physical function (SPPB[1])	Baseline	2.4	±	2.0		2.5	±	1.8		0.839
	Endpoint	2.8	±	2.2	0.115	3.8	±	2.0	< 0.001	0.016
Paper I - Other outcomes Body composition:										
Fat-free mass (kg)	Baseline	50.3	±	12.2		47.4	±	10.6		0.629
	Endpoint	46.8	±	11.9	< 0.001	48.5	±	10.8	0.021	0.278
Fat percentage (%)	Baseline	35.2	±	8.3		38.3	±	9.6		0.082
	Endpoint	36.0	±	7.4	0.014	37.0	±	7.0	0.813	0.489
Calf circumference (cm)	Baseline	34.0	±	4.5		34.9	±	4.9		0.349
	Endpoint	33.7	±	5.9	0.516	35.9	±	4.6	0.002	0.018
Mid-upper arm circumference (cm)	Baseline	28.3	±	4.0		29.8	±	5.7		0.114
	Endpoint	27.4	±	4.9	0.055	31.3	±	6.0	< 0.001	0.002
Waist circumference (cm)	Baseline	104.4	±	14.0		103.6	±	13.8		0.739
	Endpoint	101.9	±	14.4	0.004	103.7	±	13.6	0.718	0.401

		Control group (*n* = 53)				Intervention group (*n* = 53)				Between groups
Muscular strength:		**Mean**	**±**	**SD**	***P*-value**	**Mean**	**±**	**SD**	***P*-value**	***P*-value**
Handgrip strength (kg)	Baseline	21.5	±	8.5		19.7	±	6.8		0.119
	Endpoint	21.3	±	9.3	0.790	20.4	±	8.9	0.271	0.612
Dietary intake:										
ISNST[2]	Baseline	4.5	±	1.3		5.1	±	1.7		0.047
	Endpoint	3.7	±	2.2	0.004	2.0	±	1.2	< 0.001	< 0.001
Energy (kcal/day)	Baseline	1546	±	297		1493	±	360		0.412
	Endpoint	731	±	320	< 0.001	2412	±	403	< 0.001	< 0.001
Protein (g)	Baseline	77.3	±	14.8		74.7	±	18.1		0.411
	Endpoint	31.2	±	15.5	< 0.001	118.2	±	34.3	< 0.001	< 0.001
Protein (g protein/kg bw/day)[3]	Baseline	1.1	±	0.4		1.0	±	0.3		0.202
	Endpoint	0.4	±	0.2	< 0.001	1.5	±	0.4	< 0.001	< 0.001

[1]SPPB: Short Physical Performance Battery test; score range: 0–8, where a higher score represents better physical performance.
[2]ISNST = Icelandic Nutrition Screening Tool; score range: 1–30, 1–2 = low nutritional risk, 3–4 = some nutritional risk, ≥ 5 = high nutritional risk.
[3] g protein/kg bw/day = grams of protein per kilogram of body weight per day.

Table 9 – Results from Paper II

		Control group (*n* = 53)				Intervention group (*n* = 53)				Between groups
Paper II - Main outcomes		**Mean**	**±**	**SD**	***P*-value**	**Mean**	**±**	**SD**	***P*-value**	***P*-value**
EQ5D[1]	Baseline	0.7	±	0.2		0.7	±	0.1		0.852
	Endpoint	0.627	±	0.225	0.104	0.729	±	0.131	0.032	0.008
SRH[2]	Baseline	61.3	±	18.1		58.8	±	19.9		
	Endpoint	54	±	21.5	0.033	70.1	±	17.4	0.001	< 0.001
MMSE[3]	Baseline	25.9	±	2.9		26.1	±	2.8		0.702
	Endpoint	25.9	±	3	0.774	27.4	±	2.4	0.001	0.006
CES-D[4]	Baseline	5.6	±	4.7		5.4	±	4.2		
	Endpoint	8	±	4.9	< 0.001	4.7	±	3.2	0.209	< 0.001

Paper II - other outcomes: see Table 8 for the results of body weight and dietary intake.

No adverse events were noted in the intervention group for the foods, snacks and ONS provided.

[1]EQ5D = EuroQol- 5 Dimension quality of life, index ranging from -0.624 to 1.0, from very poor HRQOL to perfect HRQOL.

[2]SRH = Self-rated health; the EQ-5D instrument contains a visual analogue scale (VAS) by which participants can self-rate their health from 0 (worst health possible) to 100 (best health possible).

[3]MMSE = Mini-Mental State Examination; scores from 0 to 30, where 0–17: severe impairment, 18–24: mild impairment, 24–30: no impairment.

[4]CES-D = Centre of Epidemiological Studies Depression IOWA scale; score range: 0–22, > 9 = presence of depressive symptoms.

Table 10 - Results from Paper III

	Control (*n* = 52)				Intervention (*n* = 52)				Between groups
Paper III - Main outcomes	**Mean**	**25th per.**	**Median**	**75th per.**	**Mean**	**25th per.**	**Median**	**75th per.**	**P-value**
Emergency room visits at 1 month	0.21	0.00	0.00	0.00	0.12	0.00	0.00	0.00	0.370
Emergency room visits at 6 months	0.98	0.00	0.00	2.00	0.79	0.00	0.00	1.00	0.750
Emergency room visits at 12 months	1.69	0.00	1.00	2.00	1.40	0.00	1.00	2.00	0.911
Emergency room visits at 18 months	2.31	0.00	2.00	2.75	1.96	0.00	1.00	3.00	0.928
Readmissions at 1 month	0.19	0.00	0.00	0.00	0.02	0.00	0.00	0.00	0.015
Readmissions at 6 months	0.77	0.00	0.00	1.00	0.33	0.00	0.00	0.75	0.014
Readmissions at 12 months	1.12	0.00	1.00	2.00	0.62	0.00	0.00	1.00	0.044
Readmissions at 18 months	1.52	0.00	1.00	2.00	0.92	0.00	1.00	1.75	0.072
Length of stay of 1 month	0.92	0.00	0.00	0.00	0.02	0.00	0.00	0.00	0.013
Length of stay of 6 months	13.21	0.00	0.00	13.75	2.44	0.00	0.00	1.50	0.006
Length of stay of 12 months	19.40	0.00	3.00	21.00	5.83	0.00	0.00	7.75	0.034
Length of stay of 18 months	26.00	0.00	9.00	39.25	10.42	0.00	2.00	10.75	0.033

Paper III - Other outcomes: see Tables 8 and 9 for other outcomes. No adverse events were noted in the intervention group for the foods, snacks and ONS provided. **P*-values for the differences between groups in emergency room visits, number of readmissions and length of stay are based on the Mann-Whitney U test. *P*-values for the differences between groups regarding the proportion of participants readmitted are based on sex-adjusted logistic regression; 25th per. = 25% percentile, 75th per. = 75% percentile.
(Figure copied from **Paper III (175)**)

	Control (*n* = 52)				Intervention (*n* = 52)				Between groups
Paper III - Main outcomes	**Mean**	**25th per.**	**Median**	**75th per.**	**Mean**	**25th per.**	**Median**	**75th per.**	**P-value**
Proportion of participants readmitted at 1 month			15.8				1.9		0.033
Proportion of participants readmitted at 6 months			46.2				25		0.021
Proportion of participants readmitted at 12 months			55.8				38.5		0.051
Proportion of participants readmitted at 18 months			65.4				51.9		0.107

Paper III - Other outcomes: see Tables 8 and 9 for other outcomes. No adverse events were noted in the intervention group for the foods, snacks and ONS provided.
**P*-values for the differences between groups in emergency room visits, number of readmissions and length of stay are based on the Mann-Whitney U test. *P*-values for the differences between groups regarding the proportion of participants readmitted are based on sex-adjusted logistic regression; 25th per. = 25% percentile, 75th per. = 75% percentile.
(Figure copied from **Paper III (175)**)

6 Discussion

Malnutrition/undernutrition is a prevalent and well-known problem in hospitalised older adults that persists after discharge to independent living; thus, the need for interventions that improve the nutritional status of those affected is of utmost importance (39). Many interventions have been carried out, some with significant results, others not so. We strived to combine established methods to optimise the results of the provided nutritional intervention.

6.1 Aims

Our aims were to:

- Provide older adults at nutritional risk with an NT managed by a dietitian, using NCP, and provide them with free protein- and energy-rich foods, snacks and ONS for six months post-discharge.
- Investigate if our intervention could positively affect the nutritional status, body weight, physical function, HRQoL, SRH, cognitive function and depressive symptoms of the participants.
- Determine whether the provided intervention would be able to decrease outcomes such as hospital readmission rates, LOS, positive PNHAA and mortality, when compared to a control group discharged according to the standard current practice of Landspitali, The National University Hospital of Iceland, during the intervention and at one, six, twelve and 18 months.

Our study showed significant results in the prevention of weight loss and muscle deterioration, and significant improvements in the nutritional status and physical function of the participants in the intervention group **(Paper I).** Furthermore, we found significant improvements in HRQoL, depressive symptoms, SRH and cognitive function **(Paper II)** in the intervention group**.** Eighteen months after the last participant finished the study, we retrospectively looked at whether the intervention had affected the number of ER visits and hospital readmissions, shortened LOS and decreased mortality during the intervention phase and at one, six, twelve and 18 months. Despite the intervention lasting for six months **(Paper III),** we found that it lessened readmissions and shortened LOS, although we did not see reductions in ER visits or mortality.

6.2 The dietitian's role

Even though malnutrition and being at nutritional risk are prevalent and well-known problems in hospitalised and community-dwelling older adults, and their nutritional

status often declines after discharge, the problem is still, to a great extent, ignored within the hospital environment (11). Because the consequences of nutritional risk and malnutrition are dire, it is critical to first identify those at nutritional risk upon admission and reassess them during hospitalisation to implement a proper NT managed by a dietitian (10). Moreover, there is a need to connect those at nutritional risk at the time of hospital discharge with a dietitian who can provide transitional NT at home (10).

The dietitian is an expert in nutrition and can identify nutritional issues and treat them. This expertise is not present among other healthcare providers. This is why the dietitian plays a crucial role in improving factors related to nutritional risk before, during and after hospital discharge. Hence, the role of the dietitian has been examined in several studies and mentioned in recent guidelines for nutritionally at-risk older adults (10, 83, 156), and in a few systematic reviews and meta-analyses (36, 92, 93). These works have investigated the effects of, in most circumstances, having a dietitian provide older adults at nutritional risk with NT. They all agree that the NT intervention positively affects protein and energy intake and body weight, which agrees with our findings. However, due to diversity in the assessment tools of physical function used in the different RCTs included in the analyses, those reports did not find improvements in physical function, which we found.

We noticed an improvement not only in protein and energy intake and body weight, similar to that in the 2019 systematic review and meta-analysis by Reinders et al. (36), but also in physical function. This outcome might be attributed to the fact that our intervention lasted for 24 weeks and was a multimodal and intensive intervention, which is normally not the case as most nutritional RCTs last for 8–12 weeks and lack a multimodal approach. Such a short time might not be sufficient to improve physical function, especially considering that the study population is made up of older adults and agrees with our findings as we were able to observe improvements in physical function at the endpoint.

Other studies have also shown positive effects when providing discharged older adults with NT, which further proves the importance of the inclusion of a dietitian in the post-discharge period, where older adults are especially vulnerable to a further decline in nutritional status (71).

In an RCT on discharged community-dwelling older adults, the intervention group was provided with NT by a dietitian in the patients' homes (177). The NT provided the intervention group with three home visits from a dietitian who assessed the nutritional needs of the participants and created an individualised nutrition plan at the first home visit and reassessed it in subsequent visits, ensuring that the energy and protein needs of the participants were met (177). The RCT reported a 1.4 kg difference at the endpoint (12 weeks) between the groups, where the intervention group gained weight and the control group lost weight (177). The authors also reported an improvement in the nutritional status of the intervention group and observed positive tendencies in ADL

and HRQoL in the intervention group. Thus, they concluded that these positive results call for adding a dietitian to the aftercare of nutritionally at-risk community-dwelling older adults discharged from the hospital (177).

A 2021 RCT showed positive effects on body weight when providing discharging older adults with NT, a personalised nutrition and exercise plan, food items for the first 24 hours after discharge and ONS (178). Sixteen weeks after discharge, a significantly smaller weight loss was observed in the intervention group compared to the control group (0.7 (±4.3) vs -1.4 (±3.6), P = 0.002) (178). The multimodal approach, where the researchers are careful to respect the participants' personal choices and preferences is, in our opinion, crucial because malnutrition among older adults is multifaceted.

6.3 Nutrition Care Process

The dietitian in our study utilised the NCP along with the NCPT, with a lot of effort put into all aspects of these to be able to provide the intervention group with the best possible NT, built on evidence-based practice. Utilising the NCP is clinically recommended for all dietitians and other nutrition professionals and is the best way to systematically provide highly individualised NT while often reassessing the therapy provided (179).

NCP takes into account the individual's nutritional status, digestive, swallowing and/or chewing issues, diseases and preferences, and encourages personal choices when it comes to the types of foods, snacks or ONS used; thus, it enhances compliance to the NT (95, 179). As the effects of NT using NCP are assessed and further reassessed at each appointment with the patient, the use of NCP is crucial to be able to individualise the NT according to the changing needs and preferences of the patient (179). Because NCP provides dietitians with guidance on how to keep records of the nutrition care provided, it allows other healthcare providers to look after the patient by knowing exactly what has been done and to continue the NT prescribed.

Another important factor in using the NCP is that a nutritional diagnosis is made at each appointment, using the NCPT, which focuses on the most urgent nutritional issue at each timepoint. Subsequently, the focus can be shifted to other pressing issues when assessing the patient in future sessions. For example, the most urgent issue might be undernourishment/malnourishment at the first NT appointment. In subsequent appointments, when sufficient nourishment (most commonly protein and energy) has been established, the dietitian might start to work on other dietary issues that weren't as urgent as the undernourishment at the beginning, and in this way, structuring and prioritising nutritional matters.

The use of NCP in our study might account for our success in being able to positively affect the intervention group's nutritional status and compliance with the NT provided.

The factors that influence high compliance with nutritional interventions have been identified by Holdoway et al., who reviewed current nutrition guidelines and systematic reviews to identify the most effective ways to improve outcomes for those with disease-related malnutrition. These authors found that focusing on what matters most to the patients and involving them in their nutritional care was highly beneficial (95). Holdoway et al. identified two guidelines for older adults, the ESPEN guidelines on clinical nutrition and hydration in geriatrics (10) and a position paper by the Academy of Nutrition and Dietetics on individualised nutrition approaches for older adults (179).

When NT is provided, ESPEN recommends:

- Patient's preferences and choices should be prioritised.
- Energy and protein intake recommendations should be personalised.
- If identified as being at nutritional risk, NCP should be used.
- Food and liquid intake recommendations should be personalised and comprehensive to increase adherence and achieve the best outcomes regarding nutritional status, clinical results and HRQoL.
- Individualised NT should be provided.
- Individualised, multimodal and multidisciplinary approaches should be provided in nutritional interventions for older adults after hip fracture and orthopaedic surgery to increase their chances of adequate dietary intake and improve or maintain both clinical outcomes and HRQoL (10).

The Academy of Nutrition and Dietetics recommends:

- To include a registered dietitian (or nutritionist) in the interdisciplinary team for providing the malnourished person with NT, using the NCP, which individualises the nutritional care provided by taking into account the patient's prior medical condition/s, their personal wants and maintaining their autonomy to choose what kind of healthcare they would accept (179).

The review by Holdoway et al. (95) analysed the studies included in the systematic review by Baldwin et al. (93). As a result, Holdoway et al. found that individualisation of the nutritional intervention was reported in 63 of the 94 included studies, suggesting the use of NCP in at least some of the studies, although not mentioned specifically.

A few other studies that specifically recommended the use of NCP when providing NT to older adults were identified.

Roberts et al. recommended NT using NCP for sarcopenia, frailty and malnutrition because these conditions are linked and require similar nutritional care (180). This recommendation was shown to provide the best nutritional care to those affected, which was the goal of the current study.

Wong et al. found that providing NT to nutritionally at-risk older adults had positive

effects on several outcomes (92). These authors called for better descriptions of the NT provided in future studies (i.e., if NCP and NCPT are utilised). They also reported that the inclusion of NCP would indicate a certain standardisation of the nutritional care provided, as NCP follows standardised methods (92). We agree with Wong et al. about the importance of including better descriptions of the NT in studies that focus on providing malnourished or nutritionally at-risk older adults with such an intervention as this would help improve the available evidence for this practice.

Although not exclusively on older adults, a systematic review by Tunzi et al. (181) supported the use of NT by a dietitian applying NCP. These authors looked into the optimal frequency of NT provided by a dietitian for obtaining the best results in those receiving radiotherapy for head and neck cancer (181). They found four RCTs and deemed the optimal frequency of NT to be weekly to achieve improved outcomes regarding nutritional status, HRQoL, fewer cancer treatment interruptions/delays, fewer hospital admissions, fewer complications and fever co-morbidities (181).

6.4 Fortified foods, snacks, oral nutritional supplements and Meals on Wheels

The dietary intake of the two groups in our HOMEFOOD study did not differ significantly at the baseline, where both groups consumed ≈ 1500 kcal/day and ≈ 75 g protein/day at the hospital (172). A similar dietary intake has been reported for hospitalised older adults with COPD in Iceland (182).

At the time of recruitment, when baseline measures were taken and after randomisation, the control group was informed by members of the research team about the importance of adequate nutrition tailored to older adults and was given a pamphlet about appropriate nutrition for older adults. Despite the advice and information provided, their energy and protein consumption declined drastically. This unfortunate pattern has been observed before in Iceland, in a pilot study that investigated the nutritional status of older adults after discharge to independent living (71). In that pilot study, the mean energy intake was only 759.0 (±183.4) kcal/day and the mean protein intake was 35.1 (±7.5) 2 weeks after discharge, and thus none of the participants satisfied their protein or energy needs (71).

MOW is a food service in which people can order home-delivered food for a fee. MOW usually supplies people with one meal a day for each day an order is made. This is true for Iceland, and the one meal a day provided is prepared according to general nutritional recommendations for healthy adults, published by the Icelandic Directorate of Health (183). In 2014, a food scientist conducted an analysis for the MOW provided in Reykjavik and found that the meals had 500–850 kcal and protein was, on average, 23% of the provided meal (184). The analysis of the MOW concluded that protein and fat should be reduced and more vegetables and fruits should be supplied, which is not

concurrent with the recommendations for frail or sick older adults (156). The probable reason for this is that, even though MOWs in Iceland are mostly provided for nutritionally at-risk older adults, there are other individuals unable to cook who utilise this service. This could, for example, be disabled young adults, mentally ill individuals, or sick younger adults unable to cook.

As our participants were nutritionally at-risk older adults and undernutrition is a well-known problem for this group, we made the decision to provide energy- and protein-rich foods, snacks, and ONS to our intervention group to increase their chances of being able to fulfil their nutritional needs. This agrees with the 2022 ESPEN practical guidelines on clinical nutrition and hydration in geriatrics (10), which recommend providing older adults at nutritional risk or malnourished with both protein- and energy-enriched foods, snacks and ONS.

A recent meta-analysis investigated which components of MOW are likely to increase protein and energy intake (14). Fifteen studies were identified where MOW was provided for healthy older adults. MOW was described as a service for those having trouble shopping or cooking because of restricted mobility. The authors went on to describe MOW as providing one hot or frozen meal for each day the service was ordered by the clients. There were three studies among the 15 identified that specifically dealt with older adults and where MOW was altered from the usual one meal a day to a service better suited for this population, resulting in positive effects on energy and protein intake (103, 150, 185). All these three studies were RCTs and are mentioned below:

- One study provided protein-rich bread and meals for a 2-week period to community-dwelling older adults and significantly improved their protein intake (103).
- The second study provided home-care-receiving community-dwelling older adults with snacks in addition to their daily meals for 12 weeks, and significantly increased body weight and fat-free mass at 12 weeks; fat-free mass remained significant 3 months post-intervention (185).
- The third study provided older adults who had recently started to receive MOW with either 21 meals/week and 14 snacks/week (100% of the daily reference intake) or with five hot meals/week (a third of their daily reference intake) (150). The group that received 100% of the daily reference intake improved its nutritional status faster than the group that received a third and also decreased its nutritional risk, which the authors suggest could further positively affect the ability of the older adults to remain independent and improve physical function.

The authors suggest that those providing MOW should adjust the accessibility, diversity, tastefulness, portion size and delivery of the meals, which would in turn improve the acceptance of the foods provided and increase protein and energy intake.

They also point out that hospital admissions are short, thus increasing the urgency of providing nutritional care at home (14). This agrees with previous findings in Iceland, where the patients' nutritional status declined further after discharge from the hospital to independent living (71). In our HOMEFOOD study, the control group also exhibited a decline in their nutritional status after discharge home (172).

Another recent systematic review looked into the nutritional challenges of older adults receiving MOW (152) and found that undernutrition is prevalent among those receiving the service. The authors also found that MOW may improve dietary intake, and that, when MOW is combined with NT or snacks are added, or more than one meal/day is provided, or when meals are enriched, dietary intake increases substantially. They concluded that further development of MOW is needed to ensure sufficient dietary intake among older adults receiving the service (152). This is also reflected in our results as we provided the intervention group with a protein- and energy-rich meal, two protein- and energy-rich snacks and two ONS daily for six months, along with intense NT, which yielded convincing positive results for most outcomes.

A few more reviews and studies were identified on food fortification or MOW, and are mentioned below:

- In their scoping review, Moloney and Jarrett (99) found that by fortifying foods with protein and/or energy, an improvement in protein and/or energy intake was obtained. The methods of fortification were, for instance, providing ONS or fortifying milk or other foods.
- Dent et al. recommend early interventions and food and/or snack fortification that is palatable to the nutritionally at-risk receivers of the intervention (12).
- Ziylan et al. conducted an RCT that provided protein-fortified bread, with a positive effect (103).
- The systematic review by Sossen et al. looked at energy and protein fortification of food provided to nursing home residents and found an improved protein and energy intake (104).
- An RCT that provided protein-rich meals and dairy products saw improvements in protein intake (105).
- A review by the London-based Nutrition Society of England, where fortification of foods was recommended for older adults, based on data from 18 countries and long cohort studies (106).

Studies showing improvements in outcomes when fortification is utilised are heterogeneous in terms of methodologies, the types of foods fortified, how much food is made available and for how long.

Our results show that MOW, snacks and ONS played a role in our positive findings. Furthermore, the fact that we went to great measures to increase the chances of

adherence to the foods, snacks and ONS played a role in these results. The measures we implemented to increase adherence were to:

- Ask older adults in a nursing home what their favourite foods were.
- Develop these favourite foods into meals with Icelandic food companies, ensuring that the meals:
    - Had tender meats and the meats were cut against the muscle fibres to ensure safe chewing and swallowing.
    - Had flavours according to the traditional preferences of older adults in Iceland.
    - Had a high proportion of protein; the sauce was plentiful and made with full-fat cream, the carbohydrate proportion was low and vegetables were kept to a minimum.
    - Were provided in easy-open packages with simple cooking directions printed in large fonts.
    - Were enriched with protein and energy (including snacks and ONS).
- Conduct a sensory test with older adults and adjust the formulations according to the comments received.
- Include a variety of foods, snacks and ONS.
- Call everyone in the intervention group weekly to ask for preferences regarding the meals they were to receive the following week.
- Offer those living with the participant free meals, snacks and ONS as well to lessen the chance of the participant splitting their own meals with them.

6.5 Combination of critical/decisive factors – multimodal approach

The key to the success of our study was the combination of many components known to ameliorate malnutrition or the risk of it (i.e., NT, NCP, protein- and energy-rich free foods, snacks and ONS, and a long intervention time (six months). Thus, our study followed the multimodal approach, which allowed for the increased intake of both energy and protein for a prolonged period, resulting in significant improvements in body weight, fat-free mass, physical function, depressive symptoms, HRQoL, SRH, readmissions and LOS.

ESPEN recommends using a multimodal and multidisciplinary approach in nutritional interventions for older adults (4). This recommendation aims to increase the chances of obtaining positive effects from the intervention by ensuring that those receiving it have a sufficient protein and energy intake that in turn solves their nutritional issues. A few studies are cited to support this recommendation; one of them is multimodal, but not multidisciplinary, like our HOMEFOOD study. The multimodal study referred to in the ESPEN guideline is an RCT by Neelemaat et al., where the authors used NT, protein-

and energy-enriched food, ONS, calcium and vitamin D supplementation as their intervention, and obtained a significantly lowered incidence of falls (186), a decrease in functional limitations, and the intervention was also shown to be cost-effective (139). Even though Neelemaat et al. started the intervention while participants were still hospitalised, and our study's intervention started after discharge, both studies were multimodal and improved protein and energy intake along with other positive outcomes.

As evidenced by previous studies malnutrition is prevalent in hospitalised older adults (35, 187-189), and unfortunately, our study found that after hospital discharge, weight loss is experienced by older adults receiving standard care, as seen in our control group. Other researchers have reported similar findings (190). Additionally, our intervention, which employed a comprehensive approach to positively affect the nutritional status through several components, demonstrated greater efficacy compared to other studies that utilised a single component (i.e., ONS, MOW or NT) (13, 133, 191-194).

We did this by:

- Providing NT by a dietitian, using the principles of NCP
- Offering a diverse range of energy- and protein-rich foods, snacks and ONS at no cost
- Tailoring the food items to the individual preferences and needs of older adults

Our nutrition therapy achieved high acceptance of the provided foods all the way through the six-month period of the intervention. This resulted in sufficient energy and protein intake and an increase in body weight in our intervention group. Another important factor was that our approach protected the muscle mass of the participants. Subgroup analysis indicated consistent treatment effects across most subgroups, apart from the three BMI categories. Participants in the high BMI category experienced lower weight gain compared to those in the middle and low BMI categories. This may be attributed to the differing objectives of the NT, based on individual characteristics and needs.

The primary outcome of our study was that implementing NT with the goal of preventing malnutrition in older adults after hospital discharge led to significant improvements in various aspects of well-being. Compared to the current standard care, our findings demonstrate notable enhancements in HRQoL, SRH, depressive symptoms and cognitive function. This highlights the feasibility of integrating NT into a restructured home care system, where individuals at nutritional risk can access the services of a dietitian. By prioritising both physical and mental well-being, this approach has the potential to reduce hospital readmissions and shorten LOS, which are both associated with inadequate nutrition, thus benefiting both individuals and the healthcare system. Another important take-home message of this study is that older

adults with high BMIs should not be ignored when it comes to screening for nutritional risk and subsequently receiving NT by a dietitian if scoring at nutritional risk or being malnourished. By receiving proper NT, the person with a high BMI would get an individualised approach with a focus on weight stabilisation like the participants in the high BMI category of our study did, resulting in the prevention of weight loss and preservation of fat-free mass. This agrees with the ESPEN guidelines on clinical nutrition and hydration in geriatrics that recommend that weight-reducing diets should be avoided for those with high BMIs to prevent potential loss of muscle mass and the resulting decline in functional abilities (10).

Given that our intervention involved a series of five home visits conducted by our dietitian and food items were delivered weekly over a span of 6 months, with the addition of phone calls to the intervention group, it is reasonable to not only attribute the positive outcomes to the increased protein and energy intake. Previous studies have indicated that increased social interactions, such as those facilitated by home visits, phone calls and deliveries, are associated with improved quality of life (195), enhanced cognitive function (196) and reduced symptoms of depression (197). Therefore, it is plausible that the positive outcomes observed in our study can be partially attributed to the heightened social interactions resulting from home visits and food deliveries. Nevertheless, our findings indicate that changes in body weight are associated with improvements in three out of the four outcome variables. This suggests that the increase in dietary intake and the physiological changes resulting from it may have played a role in the observed positive outcomes.

Finally, an important consideration is the generalisability of the study results because the study population included only a fraction of the screened population. Exclusion from participation in our study was mainly due to not having permission to recruit in the hospital units where potential participants were moved to, or that the individuals were too sick to participate (n = 534) or that the potential participant had low cognitive function with an MMSE < 20 (n = 181). The use of low cognitive function as an exclusion criterion is a standard practice in study design and is mandated by ethical committees to safeguard potential participants from interventions they may not comprehend or be able to follow.

6.6 Importance of preventing weight loss

Increasing body weight in older adults who are underweight (BMI < 22) and preventing weight loss in others by ensuring that dietary and protein intake is sufficient to avoid the negative consequences of malnutrition is critical. The protection of one's body weight is important to:

- Preserve or improve physical function
- Preserve muscle mass/fat-free mass

- Maintain HRQoL
- Maintain SRH
- Maintain cognitive function
- Decrease depressive symptoms

These are all important points for the independence of older adults and their overall well-being; thus, we must focus our efforts and attention on developing multimodal and multidisciplinary nutritional interventions that can truly affect these outcomes.

Our HOMEFOOD study prevented weight loss and our intervention group had a significant weight gain from the baseline to the endpoint of 1.7 kg ± 2.5 kg. With only one individual in our intervention group losing >1 kg of body weight and with 42 in the control group losing >1 kg of body weight, we can assume that both the multimodal approach along with a study period of 6 months is a successful way to tackle the issue of weight loss.

6.7 Importance of the intervention on major outcomes

Hospital stays and readmissions are a vicious cycle for older adults because they not only mean that the patient is ill enough to be admitted to the hospital, but hospital stays themselves are associated with several negative outcomes. For instance, during hospital stays, the nutritional status, HRQoL, ADL and overall health decline (198, 199). Moreover, hospital stays/readmissions carry the burden of increased costs (200). These are all reminders of why interventions that can potentially reduce hospital readmissions and shorten LOS are critical (201).

The risk reduction (relative risk) we found for readmission in our intervention group was 21–88%, with less reduction as time went by and got closer to the 18-month study mark. As our intense nutritional intervention lasted for six months, we expected a gradual decrease in the intervention's effects as we drew closer to the end of the study (18 months).

A recent systematic review and meta-analysis of RCTs by Lærum-Onsager et al. focused on the effects on readmission rates when discharged older adults received nutrition and/or exercise interventions as a continuation of their hospital stay. As a result, nutritional intervention RCTs, but not exercise intervention RCTs, lowered the risk of readmission (16%) (202).

Neelemaat et al. looked at survival at one- and four-years post-intervention and found that there was no significant difference in the survival of the control and intervention groups (203). We were unable to detect a statistical difference in mortality between our groups up to 18 months post-intervention, which raises the question, 'At what timepoint of the nutritional risk/malnutrition trajectory of older adults would a nutritional intervention be most effective to lessen mortality?'. The answer might be that the implementation of a nutritional intervention should be shifted to an earlier time, or as

soon as an older adult is screened to be at nutritional risk. This could be done by screening older adults for nutritional risk regularly within the healthcare system, as recommended by several nutrition societies (6, 10), and nutritional interventions could be started immediately using a multimodal approach.

We were successful in lessening readmissions at one, six and twelve months and shortening LOS in our intervention group at all timepoints, which further supports our hypothesis that a multimodal nutritional approach would be preferable to a single-component intervention, which has shown unclear results on these outcomes. Kruizenga et al. (45) reported that undernourished hospitalised individuals had a 1.4-day longer LOS than those who were well-nourished during hospitalisation. In our study, LOS was 0.92 (control group) vs 0.02 days (intervention group) at one month, 13.21 vs 2.44 days at six months, 19.40 vs 5.83 days at twelve months and 26.00 vs 10.42 days at 18 months.

We were able to increase the dietary intake and improve physical and mental well-being in the intervention group by supplying an intense, multimodal nutritional intervention, and having it last for 6 months post-discharge, which likely explains why we also observed a reduction of readmissions. Another important factor that might contribute to the reduction of readmissions might be that our intervention creates a nice transitional nutritional care for nutritionally at-risk older adults. Patients go from receiving regular meals at the hospital to receiving NT and free food supplied to them when returning to their homes.

Another interesting observation regarding the readmission rates of our control group (18% at one month and 77% at six months, see Table 3 in **Paper III**) is that their rates were higher than those previously reported (204-207). This indicates that not only there is a need for nutritional support post-discharge for nutritionally at-risk older adults, but also, the formal assistance provided in Iceland after discharge might not be sufficient when compared to formal care in other countries, which might result in higher readmission rates.

Nonetheless, we were not able to lessen the chance of getting a positive nursing home pre-admission assessment, which implies that our participants might have already been too impaired by a poor nutritional state (which developed in previous months or even years) to be able to affect this outcome. The number of ER visits was not statistically different either, which reflects the fact that the first choice when someone is sick or experiencing syncope or falls in Iceland is to go to the ER.

As mentioned earlier in this dissertation, in 2022, the Ministry of Finance and Economy of Iceland reported that (31):

≈ 48.8 billion ISK of the ≈ 71 billion ISK spent on healthcare services accounts for hospital stays.

≈ 15.2 billion ISK annually accounts for stays in nursing homes.

≈ 4.3 billion ISK is spent annually in day-stay centres.

≈ 2.0 billion ISK is spent annually for formal care rendered by social services and/or home-care nurses (31).

These numbers show that the greatest benefit could be achieved by lowering the cost of hospital stays. In 2021, the Ministry of Health of Iceland reported on the future development of services of Landspitali, The National University Hospital of Iceland (208). They reported 1295 admissions to the geriatric wards of Landspitali in 2019, resulting in a 101% utilization of the ward's beds (208). Older adults are, however, also present in other wards (e.g., pulmonary ward, cancer wards, department of orthopaedics and more) (208). Older adults (≥ 75 years) have on average an 85% longer LOS, compared to those younger than 75 years (208). Thus, finding interventions that can lower LOS and costly readmissions would increase the physical and mental ability of older adults and would enable them to take care of themselves within their own homes, perhaps with the addition of increased formal care (208).

6.8 Strengths and limitations

Our study has several strengths, being an RCT with a low dropout rate and specialised protein- and energy-rich foods, snacks and ONS, where we were able to carry out the intervention without missing any deliveries or NT sessions to all 52 participants in the intervention group. The inability to double-blind a study like this is an unfortunate limitation, but we feel that, as the assessments of our outcomes were single-blinded along with the data inputs, we were able to counteract this weakness.

The multimodal approach is a strength of the HOMEFOOD study. We utilised an intense NT (five home visits and three follow-up phone calls) supplied by a dietitian using the NCP and NCPT. As part of the NCP, we provided protein- and energy-dense foods, snacks and ONS free of charge, which had gone through testing to ensure palatability and ease of consumption. Another strength of this study is that, along with the multimodal and intense NT approach, the intervention was provided for a fairly long period of time (six months), which is a novelty among recent RCTs providing nutritional interventions after hospital discharge.

Although the sexes were not evenly distributed between the groups, neither our unadjusted nor adjusted outcomes differed, with almost all participants losing weight in the control group and the opposite being true in the intervention group. This outcome suggests that the sex of the participants cannot account for the differences in outcomes

observed between the intervention and control groups. We used a valid randomisation method. Other limiting factors were at-home measures, which limited our ability to fully assess gait speed (a component of the physical function assessment) and left us with no option but to measure body composition using a handheld BIA instead of a hand-foot BIA, which may be more accurate. We did, however, counteract this by measuring all participants in the same way, employing the same tools in a methodical manner and adding the measures of the circumference of the waist, upper arm and calves of our participants to strengthen our BIA findings.

6.9 Future perspectives

This doctoral dissertation has presented positive results on both clinically relevant outcomes but also on human-relevant outcomes for malnourished or nutritionally at-risk older adults discharged home from the hospital. We believe that our intervention should be used in clinical practice right away to ensure better outcomes for the patients and for cost-effectiveness. Fewer readmissions and a shorter LOS would lower the cost for the healthcare system in general but also on an individual level.

There are, however, important matters that still need to be considered for future studies:

- There needs to be an improvement in nutritional screening within the hospital and at healthcare centres to be able to start interventions to prevent malnutrition before it becomes a problem.
- Healthcare staff needs to be taught about the importance of adequate nutritional status for better patient outcomes.
- Awareness of nutritional issues should be generalised within the healthcare system.
- Future studies should consider inviting those with a lower MMSE to participate and have their caregivers involved.
- Further research is needed to determine whether a multimodal and multidisciplinary approach might be able to render substantial results in lowering mortality rates and lengthening the time older adults can be home-dwelling, thus delaying nursing home admission. In **Paper III** we did not find a positive result on these outcomes.
- For MOW services in Iceland, it would be beneficial to enrich the provided meal with protein and energy and to add 1–2 snacks to the meals delivered daily. As the group that orders MOW is often unable to cook and is at nutritional risk, it needs more than one meal a day.
- Cost-effectiveness should be calculated before providing the intervention to discharging patients at nutritional risk to decide whether implementation should be started immediately.

- Feasibility studies on the optimal timing of intervention for nutritional risk should be conducted, as it is easier to prevent malnutrition than to treat it, but a crucial factor for this is that nutritional screening needs to be performed in a timely manner at all stages of healthcare. If prevention were our focus, even greater effects may be attained.
- For future studies, it would be preferable to determine whether strengthening exercises along with a nutritional intervention would be able to increase muscular strength in nutritionally at-risk older adults.

The potential participants who were excluded because they were too sick or were moved to other hospital units could, in our opinion, have benefited from our intervention because adequate nutrition is a necessity for them as well.

In summary, the current study conducted at the University of Iceland reveals the positive effects of the proposed dietary intervention on various outcomes among older adults at risk of malnutrition or malnourished. However, we should note that the primary healthcare sector was not directly engaged in the intervention because successful implementation of the current approach as a standard care practice would require the primary sector to take the lead. With such success, we could look at a brighter future for both older adults at risk of malnutrition or malnourished and the healthcare sector, in turn providing benefits for society as a whole.

7 Conclusions

Our study shows that the standard care given to older adults at nutritional risk, who are discharged from the hospital to independent living is insufficient because those discharged have a hard time fulfilling their protein and energy needs after returning home.

This situation worsens the nutritional status of this population, leading to weight loss, the subsequent loss of fat-free mass and a deterioration of both their mental and physical well-being.

However, we found that when nutrition therapy (NT) was provided by a dietitian, the participants showed an improvement in nutritional risk, body weight, physical function, dietary intake, cognitive function, health-related quality of life (HRQoL), depressive symptoms, reduced readmissions and length of hospital stay (LOS). The NT involved the Nutrition Care Process (NCP) and its terminology (NCPT), along with the provision of energy- and protein-rich foods, snacks and oral nutritional supplements (ONS) free of charge for six months after hospital discharge.

The abovementioned health improvements represent critical and clinically relevant outcomes for the individual, the healthcare system and society as a whole.

Our study indicates that NT is an important factor in improving care for older adults at nutritional risk or malnourished at all healthcare levels. We hope to see a change in both the knowledge and treatment of older adults at nutritional risk in the future.

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Paper I

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ARTICLE OPEN

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Health issues and nutrition in the elderly

HOMEFOOD randomized trial—beneficial effects of 6-month nutrition therapy on body weight and physical function in older adults at risk for malnutrition after hospital discharge

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BACKGROUND/OBJECTIVES: Malnutrition is common among older adults. Dietary intervention studies in older adults aiming to improve anthropometrics measures and physical function have been inconsistent. We aimed to investigate the effects of nutrition therapy in combination with home delivered meals and oral nutritional supplements (ONS) in community-dwelling older adults discharged from hospital.

METHODS: A total of 106 participants (>65 years) were randomized into the intervention group ($n = 53$) and into the control group ($n = 53$). The intervention group received individual nutrition therapy (five in person visits and three phone calls) and freely delivered energy- and protein- rich foods, while the control group received standard care. Dietary intake, anthropometrics, and short physical performance battery (SPPB) were assessed at baseline and at endpoint.

RESULTS: Energy intake at baseline was similar in both groups (~1500 kcal at the hospital) but there was a significant increase in energy intake and body weight in the intervention group (+919 kcal/day and 1.7 kg, $P < 0.001$ in both cases) during the study period, compared to a significant decrease in both measures among controls (−815 kcal/day and −3.5 kg, $P < 0.001$ in both cases). SPPB score increased significantly in the intervention group while no changes were observed among controls.

CONCLUSIONS: Most Icelandic older adults experience substantial weight loss after hospital discharge when receiving current standard care. However, a 6-month multi-component nutrition therapy, provided by a clinical nutritionist in combination with freely delivered supplemental energy- and protein-dense foods has beneficial effects on body weight, physical function, and nutritional status.

STUDY REGISTRATION: This study was registered at ClinicalTrials.gov (NCT03995303).

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INTRODUCTION

Malnutrition, which is commonly observed among older adults [1, 2], is strongly associated with altered body composition, diminished physical and mental function as well as other adverse clinical outcomes. There is, however, some evidence from observational studies that aging per se is not inevitably associated with malnutrition and that appropriate dietary intake and adequate nutritional status is strongly associated with a reduced risk of mobility limitations and improved quality of life [3–5]. Hospitalizations are usually short as the health care system is overburdened, and if malnutrition is diagnosed in a patient, there might not be enough time to reverse poor nutritional status during the hospital stay. This should shift the emphasis of treatment to the patient's home after hospital discharge [6].

In older adults discharged from hospital, there are several options which can potentially help to improve dietary intake, e.g., Meals on Wheels (MOW), oral nutritional supplements (ONS) or nutrition therapy provided by a clinical nutritionist/dietitian. According to a recent systematic review [7], MOW interventions in older adults showed significant improved effects on total energy intake and the number of consumed meals/day to be important. Only three studies out of twelve in this review reported outcomes on functional measures, which are more relevant than simple measures of absolute energy intake. In Iceland, standard care among older adults after discharge from hospital is to be able to order MOW, supplying one hot meal a day, but a recent study suggests that such service may be inadequate for frail and sick older adults at nutritional risk [8].

The use of ONS is another way to improve nutritional status but meta-analyses of such interventions have only shown modest benefits with respect to weight gain (~1.0 kg) and improvements in nutritional status [9]. However, there is some suggestion that

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inclusion of dietary counselling in such interventions might increase efficacy of these two outcomes [8, 10–15].

Very few studies have investigated the combined effects of nutrition therapy and the use of ONS in older adults. Thus, we conducted a 6-month randomized controlled dietary intervention study with the aim of investigating the effects of nutrition therapy provided by a clinical nutritionist following the principles of the Nutrition Care Process (NCP) [16]. This involved access to freely delivered supplemental energy- and protein-dense foods and ONS in community-dwelling older adults discharged from hospital.

SUBJECTS AND METHODS

Study design

The HOMEFOOD study was a 6-month, randomized controlled, assessor blinded intervention trial conducted in older adults (age 66–95 years) recruited in the Reykjavik capital area, Iceland between January 2019, and July 2020. The primary aim was to investigate the effects of intense nutritional therapy, including free access to energy- and protein-dense foods delivered to subjects recently discharged from hospital. The primary outcomes of this trial were changes in body weight and physical function (Short Physical Performance Battery (SPPB)). Body weight loss and poor physical function are both important predictors of negative health outcomes in older adults [2, 17]. These two variables were chosen to be the primary outcomes, as a nutrition intervention with focus on increasing energy- and protein intake is likely to affect body weight and physical function [4, 18], considering the low energy intake previously reported in elderly discharged patients [19]. Secondary outcomes included other anthropometric measurements, nutritional status, muscular strength, dietary intake, exercise, and reported food-related digestion issues, such as diarrhoea, nausea, constipation, or stomach pain.

Reporting, approval, and funding

This study was conducted and reported according to the Consolidated Standards of Reporting Trials guidelines for Randomized Trials of Nonpharmacologic Treatments (CONSORT) [20]. 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 performed in accordance with the Declaration of Helsinki [21]. The study was registered at ClinicalTrials.gov (NCT03995303).

Screening and recruitment

Potential participants ($N = 1003$) were screened by a clinical nutritionist in collaboration with attending nurses at the Landspitalinn University Hospital of Iceland. Eligible patients were discharging home to independent living from the hospital, aged 65 years or older, and assessed as being at risk for malnutrition (score ≥ 3) according to the validated Icelandic Nutrition Screening Tool [22], and had given their written informed consent. Excluded were those with known dietary allergies/being on a special diet, severe chronic kidney disease (glomerular filtration rate < 30 mL/min/1.73 m^2), in active cancer treatment, receiving tubal feeding, not being able to communicate with the research team, cognitive function ≤20 according to the Mini Mental State Examination (MMSE) [23], and not having access to a functioning kitchen at home (i.e., refrigerator, oven, or microwave oven). Of the 1003 screened potential participants, $n = 897$ were ineligible for participation in the study. They were ineligible as they were too sick to participate, had been discharged, deceased, scored <20 on the MMSE, had been admitted to a nursing home, were not community dwelling, relying on tubal feeding, were <65 years of age, were not living in the capital area, or had declined participation (Fig. 1).

Randomization

The participants were randomly allocated to either the intervention or the control group by using a random number generated as implemented by the Statistical Package for the Social Sciences (SPSS, version 26.0, SPSS, Chicago, IL, USA).

Intervention group

The participant received nutrition therapy from the clinical nutritionist consisting of five home visits (1 day after discharge and one-, three-, six- and twelve weeks later) and three telephone calls in between the home visits. The nutrition therapy was implemented following the principles of Nutrition Care Process, which entails the following: nutritional assessment, diagnosis, intervention, monitoring, and evaluation of the nutrition therapy [16]. During the dietary counselling sessions, family members, relatives, friends, or home-care workers were invited to join as well. At the initial visit after discharge, the participant was educated about the importance of adequate energy and protein intake [24]. Nutrition-related problems were identified during the interviews, and suggestions given to resolve them. In addition to the dietetic counselling, participants received free supplemental energy- and protein-rich foods (1 hot meal/day and 2 in-between-meals/day; Supplementary Table 1) delivered once a week. 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.

Control group

At discharge, the control group received a booklet on good nutrition during aging published by The Icelandic Medical Directorate [24] and were encouraged to order MOW without any further dietary counselling during the study period, reflecting current standard care in Iceland for older adults discharged from hospital.

Participant characteristics

Background variables, e.g., age, sex, education, living arrangements, alcohol use and smoking habits, were assessed using questionnaires. Additional variables were collected from the Icelandic electronic hospital registry SAGA (TM software 3.1.39.9), e.g., height, number of diagnoses according to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10), and number of different medications.

Outcomes assessed

All primary and secondary outcome measurements were conducted at baseline (at the hospital) and at endpoint (at the participants' homes). These measurements were conducted in a predefined order and questions on food or diet were asked only at the very end of each 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 anthropometrics, physical function, muscular strength, and nutritional status were blinded.

Anthropometrics. Body weight was measured in light underwear/clothing on a calibrated scale (model no. 708, Seca, Hamburg, Germany) and height was taken from the Icelandic electronic hospital registry SAGA (TM software 3.1.39.9). Body mass index (BMI) was calculated from the height and weight (kg/m^2). Participants were categorized into three BMI categories: low BMI < 23 kg/m^2, middle BMI 23–30 kg/m^2, or high BMI ≥ 30 kg/m^2 [24]. Body composition was measured using a hand-held bioelectrical impedance analysis device (BIA, Omron HBF-306C, Kyoto, Japan) [25]. Calf circumference was measured in a seated position. The tape was wrapped around the right calf and moved up and down to locate the maximum circumference in a plane perpendicular to the long axis of the calf [26]. Midarm circumference was also measured in a seated position and was taken on the left upper arm, at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromion) [27].

Physical function. Physical function was assessed using the SPPB, which evaluates lower extremity function assessing (1) usual-paced gait speed over a four-meter-course, (2) standing balance, and (3) time to rise from a chair five times. For each test, a score of 0 to 4 is assigned using cut points [28]. The three test scores are summed, yielding a range from 0 to 12. As SPPB testing in this study was performed at the participants' homes, it was shortened for practical reasons, and thus did not include the gait speed part. The possible score therefore ranged from 0 to 8. Additionally, participants were asked the question "Do you have difficulties walking?" (Yes vs. no).

Muscle strength. Handgrip strength was measured in a seated position with a hydraulic hand dynamometer (Baseline® Baseline Evaluations Corporation) set on position two and the maximal grip strength of two trials was registered as the subject's grip force in kilograms using their dominant hand [27].

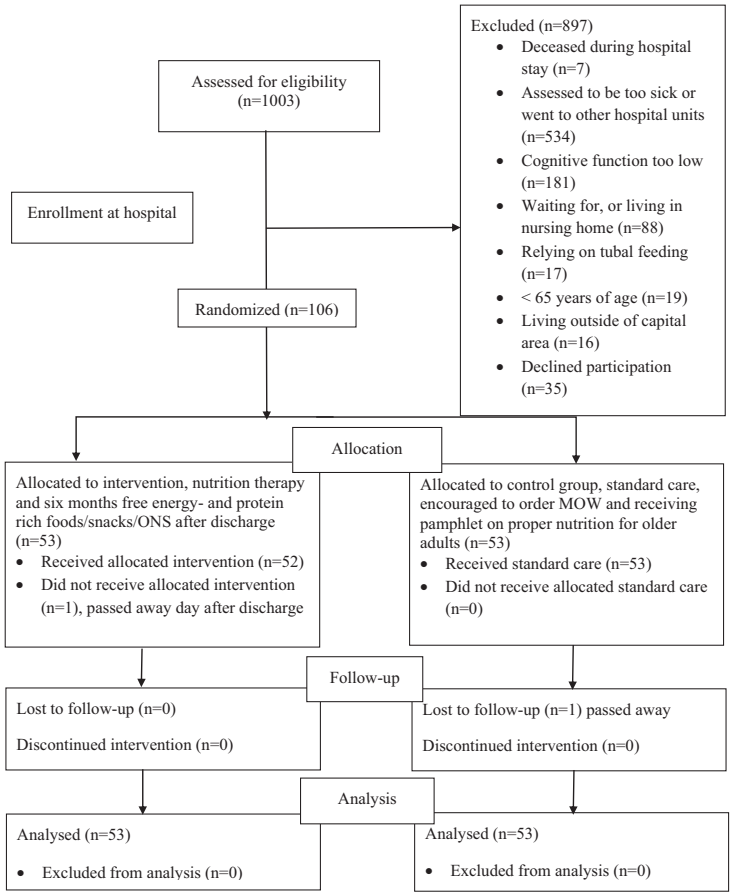

Fig. 1 Flow chart. Flow chart of assessment, recruitment, allocation, follow up, and analysis process.

Dietary intake

Dietary intake was assessed using a 24-hour-dietary-recall interview (24-HR) to obtain estimates of intakes of fluids, energy, and energy-giving nutrients [29–34]. The results from the 24-HR were entered into the nutrition calculation program ICEFOOD originally developed for the National Survey of Icelandic Diet 2002 and continuously updated for consequent National Surveys of Icelandic Diet (2011 and currently ongoing) [35]. 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 [35, 36]. Additional food-related questions and frequency of intakes of hot meals, major food groups, and liquids were assessed at endpoint using a simple food frequency questionnaire [37].

Nutritional status and food-related adverse events. Nutritional status was assessed using the Icelandic Nutrition Screening Tool as recommended by the Icelandic Medical Directorate of Health [24]. This validated questionnaire [22] consists of 13 questions which are scored and summed, yielding a range from 0 to 30. A clinical nutritionist also assessed whether any food- related digestion issues, such as diarrhoea, nausea, constipation, or stomach pain, were experienced during the intervention.

Sample size considerations

Sample size calculations based on our previous studies on body weight change [19, 38] suggest that the number of participants $n = 44$ in each group was estimated to be sufficient to detect a body weight difference of 1.8 ± 3.0 kg between groups as significant. The corresponding numbers for SPPB were $n = 45$ in each group, detecting a significance by 1 as significant (assuming SD = 1.7) [39]. The recruitment of >50 participants in each group allowed around 10% drop out to still retain sufficient statistical power.

Statistical analysis

Data were analysed using statistical software (SPSS, version 26.0, SPSS, Chicago, IL, USA). Data were checked for normality 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). We used intention-to-treat analysis.

Despite randomization, sex distribution was slightly uneven between treatment and control groups. As a result, we corrected for sex in all multivariate statistical endpoint analyses. Unadjusted analyses are also presented for comparison as supplemental material (Supplementary Table 2). Differences in anthropometrics and physical outcomes (continuous variables) between the groups at endpoint were assessed using linear mixed models in SPSS. Results are shown as parameter estimates, in which B describes the estimated and adjusted differences in the outcome variables between groups.

Differences in the abilities to perform physical tasks (single items from SPPB and "Do you have difficulties walking?" all categorical variables, yes vs. no) between the groups at endpoint were assessed using a logistic

Table 1. Characteristics of the participants.

Variables	Control ($n = 53$) Mean ± SD	%	Intervention ($n = 53$) Mean ± SD	%	*P*-value[a]
Age (years)	81.8 ± 6.0		83.3 ± 6.7		0.228
Female		52.8		71.7	0.045
Higher education (yes)		66.0		69.8	0.677
Lives alone (yes)		62.3		66	0.685
Alcohol (yes)		45.3		37.7	0.43
Smoking (yes)		9.4		3.8	0.241
ISNST score	4.5 ± 1.3		5.1 ± 1.7		0.047
MMSE score	25.9 ± 2.9		26.1 ± 2.8		0.702
No. of ICD-10 diagnoses	10.5 ± 3.8		10.3 ± 4.9		0.877
No. of medications	12.4 ± 4.2		12.2 ± 5.8		0.893
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
Waist circumference (cm)	104.4 ± 14.0		103.6 ± 13.8		0.739
Mid arm circumference (cm)	28.3 ± 4.0		29.8 ± 5.7		0.114
Calf circumference (cm)	34.0 ± 4.5		34.9 ± 4.9		0.349
Fat free mass (kg)	49.1 ± 11.9		48.1 ± 10.2		0.629
Fat percent (%)	35.2 ± 8.3		38.3 ± 9.6		0.082
Handgrip strength (kg)	21.5 ± 8.5		19.7 ± 6.8		0.119
SPPB (score)	2.4 ± 2.0		2.5 ± 1.8		0.839

BMI body mass index, *ICD-10* International Statistical Classification of Diseases and Related Health Problems 10th Revision, *ISNST* Icelandic Nutrition Screening Tool, *MMSE* Mini Mental State examination, *SPPB* short physical performance battery.
[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.

regression model, in which we corrected for the corresponding baseline values and sex.

Subgroup analysis was performed by comparing body weight changes between intervention and control in subgroups of males vs. females, married/cohabitating vs. single/divorced/alone, and low BMI group vs. middle BMI group vs. high BMI group. The effects of the intervention within subgroups were investigated using an independent samples' *t*-test (for two variable subgroups) or ANOVA including LSD post hoc test (for three variable subgroups). We tested for interaction between subgroups and intervention using a general linear model.

Endpoint calculations represent per-protocol analysis with those dropping out of the intervention included in the baseline, but not in endpoint assessment. The level of significance was set at $P < 0.05$.

RESULTS

During the recruitment period, 1003 subjects were screened and of those 106 were recruited and randomized. 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 (with exception of the one dropout) received five home visits and three phone calls. No discomfort or adverse events relating to the intervention were observed among study participants.

Baseline characteristics of the participants are shown in Table 1. The intervention and control groups were similar in most measures, with the exception that there were significantly more females in the intervention group compared to controls (72 vs 53%). In agreement with this uneven sex distribution, the intervention group also had a higher body fat percentage (borderline significant).

Concerning the primary outcome, individual changes in body weight for participants in both groups are shown in Fig. 2. The intervention group experienced in absolute terms significant weight gain during the intervention period (1.7 kg ± 2.5 kg; which equals approximately 2% of body weight, 1 out of 53 individuals lost >1 kg body weight), while significant weight loss was observed among controls (−3.5 ± 3.9 kg; which equals approximately 5% of body weight, 42 out of 53 individuals lost >1 kg body weight). After adjustment for sex (Table 2) this corresponded to 5.1 kg (95% CI: 3.9, 6.4) higher body weight in the intervention group at endpoint compared to controls. The corresponding adjusted difference in lean body mass was 4.2 kg (95% CI: 2.7, 5.6). For other anthropometric outcomes, i.e., BMI, waist-, midarm- and calf circumference, the sex adjusted differences between groups showed significantly lower values in the control group (Table 2).

As expected, the highest increase in body weight was observed in participants in the low or middle BMI categories (Table 3). The unadjusted means for all anthropometric measures at baseline and endpoint are also shown in Supplementary Table 2.

With respect to measures of physical function, the SPPB score was significantly higher in the intervention group at endpoint (Table 2) and subjects in the intervention group were also more likely to improve in single physical performance tasks at endpoint (adjusted results in Table 4 and unadjusted results in Supplementary Table 2). Handgrip strength did not differ statistically between the groups at endpoint (Table 2).

In terms of nutritional status, the Icelandic Nutrition Screening Tool score at endpoint was significantly higher (higher score corresponds to a worse nutritional status) among controls compared to the intervention group (Table 2). No difference in

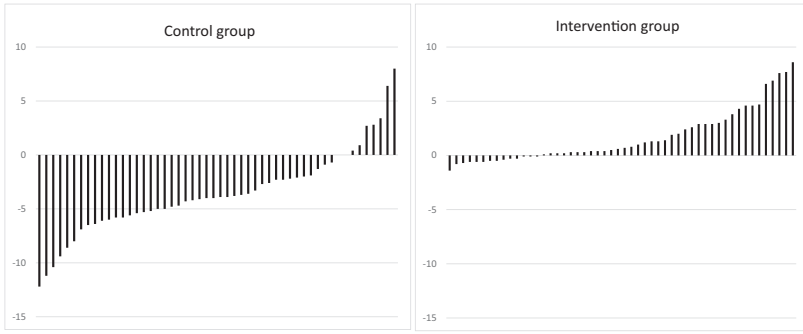

Fig. 2 Individual weight changes. Individual crude body weight changes (in kg) 6 months after discharge in the control group and in the intervention group.

Table 2. Sex adjusted differences in anthropometrics and physical outcomes between the groups at endpoint[a].

Outcome variable at endpoint	Groups	B	95% CI	*P*-value
Body weight (kg)	control vs. intervention	−5.121	(−6.381, −3.860)	<0.001
Body mass index (kg/m^2)	control vs. intervention	−1.693	(−2.167, −1.220)	<0.001
Waist circumference (cm)	control vs. intervention	−2.624	(−4.506, −0.743)	0.007
Mid arm circumference (cm)	control vs. intervention	−2.185	(−3.212, −1.158)	<0.001
Calf circumference (cm)	control vs. intervention	−1.266	(−2.33, −0.190)	0.020
Body fat (%)	control vs. intervention	1.260	(−0.575, 3.096)	0.176
Lean body mass (kg)	control vs. intervention	−4.181	(−5.647, −2.715)	<0.001
Hand grip strength (kg)	control vs. intervention	−0.871	(−3.124, 1.155)	0.401
SPPB (score)	control vs. intervention	−0.906	(−1.787, −0.293)	0.024
ISNST score)	control vs. intervention	2.226	(1.381, 3.071)	<0.001

ISNST Icelandic Nutrition Screening Tool, *SPPB* short physical performance battery.
[a]Based on linear mixed model adjusted for sex.

Table 3. Sex adjusted subgroup analysis of the main treatment effect (weight change during study period).

	Control		Intervention[a]		
		mean ± SD		mean ± SD	*P*-value[b]
All ($n = 106$)	$n = 53$	−3.46 ± 3.92	$n = 53$	1.69 ± 2.46	<0.001
Female ($n = 66$)	$n = 28$	−2.64 ± 4.32[a]	$n = 38$	1.58 ± 2.51	<0.001
Male ($n = 40$)	$n = 25$	−4.38 ± 3.27	$n = 15$	1.85 ± 2.41	<0.001
Married/cohabitation ($n = 38$)	$n = 20$	−4.14 ± 3.81[a]	$n = 18$	1.04 ± 1.90	<0.001
Single/divorced/alone ($n = 78$)	$n = 33$	−3.06 ± 3.99	$n = 35$	1.97 ± 2.67	<0.001
Low BMI category ($n = 21$)	$n = 12$	−2.19 ± 3.71[c]	$n = 9$	4.42 ± 2.76	<0.001
Middle BMI category ($n = 59$)	$n = 30$	−4.42 ± 3.97	$n = 29$	1.43 ± 2.16	<0.001
High BMI category ($n = 26$)	$n = 11$	−2.25 ± 3.57	$n = 15$	0.43 ± 1.47	0.036
Age tertile 1 ($n = 36$)	$n = 21$	−3.21 ± 4.34[a]	$n = 15$	1.66 ± 2.89	<0.001
Age tertile 2 ($n = 40$)	$n = 19$	−3.15 ± 4.28	$n = 21$	1.69 ± 2.39	<0.001
Age tertile 3 ($n = 30$)	$n = 13$	−4.34 ± 2.58	$n = 17$	1.62 ± 2.29	<0.001

[a]no significant differences in the treatment effects between the subgroups, e.g., no difference between men and women (reads vertically).
[b]*P*-value is based on an independent samples t-test for the difference between control and intervention (reads horizontally)
[c]Significant differences in the treatment effects between the subgroups according to ANOVA including LSD post hoc test: weight gain (Low BMI) > weight gain (Middle BMI) = weight gain (High BMI). Interaction term in linear analysis $P = 0.027$.

dietary intake between the two groups were detected at baseline (i.e., at the hospital) but energy and macronutrient intake increased significantly in the intervention group and decreased significantly in the control group during the intervention period (Table 5). In the intervention group, ONS provided 24 and 29% of the total energy and protein at endpoint (which equals approximately 1.75 ONS servings/day), respectively. At endpoint, more than 94% of the intervention group also stated that they

Table 4. Likelihood of improvement in performing physical tasks at endpoint adjusted for sex[a].

Outcome variable[b]	Groups	OR (95% CI)	*P*-value
Being able to perform "side-by-side"	intervention group ($n = 53$)	3.15 (0.98, 10.10)	
	control group ($n = 53$)	1	0.052
Being able to perform "semi-tandem"	intervention group ($n = 53$)	3.77 (1.45, 9.80)	
	control group ($n = 53$)	1	0.007
Being able to perform "tandem"	intervention group ($n = 53$)	2.21 (0.95, 5.10)	
	control group ($n = 53$)	1	0.065
Being able to perform "chair test"	intervention group ($n = 532$)	2.02 (0.80, 8.55)	
	control group ($n = 53$)	1	0.137
Having difficulties walking – yes[c]	intervention group ($n = 53$)	0.34 (0.14, 0.83)	
	control group ($n = 53$)	1	0.018

[a]Based on logistic regression. Adjusted for baseline values and sex.
[b]Physical tasks are single items from the Short Physical Performance Battery as well as the single question "Do you have difficulties walking?"
[c]Having difficulties to walk is not an improvement but a deterioration.

liked the provided food, reported a higher frequency of hot meals consumed, more frequent consumption of meat, and a higher intake of liquids compared to controls. No food related digestion issues, such as diarrhoea, nausea, constipation, or stomach pain were reported.

In terms of stability analyses our analyses indicated (Table 3) that neither sex, marital status, nor participant age affected the efficacy of the intervention. However, body weight changes differed by BMI categories and interaction between BMI categories and intervention was significant ($P = 0.027$).

DISCUSSION

In this 6-month randomized, controlled intervention we examined the effects of nutrition therapy provided by a clinical nutritionist following the principles of NCP [16] in combination with freely delivered supplemental energy- and protein-dense foods in older adults after discharge from hospital. We found that this nutrition intervention had strong beneficial effects on body weight and other anthropometric measures; as well as SPPB score, and nutritional status. The observed effects in our study were more pronounced than what has been reported in previous nutritional interventions not combining ONS, MOW, and nutrition therapy from a nutritionist.

Changes in body weight were observed in both groups, with an average of 5.1 kg higher body weight (which equals roughly a 7% difference in body weight) among those receiving the intervention, who gained a moderate amount of weight, compared to controls, who lost weight, which agrees with changes in dietary intake recordings after hospital discharge. The fact that 42 out of 53 of participants in the control group lost more than 1 kg body weight while only one individual in the intervention lost that much weight demonstrates that individual and targeted nutrition therapy in combination with the provision of ONS and MOW, can largely prevent negative alterations in body weight after hospital discharge.

There are currently no studies available in public literature that use the combination of nutrition therapy, home delivered food, and ONS in older adults which would allow direct comparison of the results. However, two recent trials using three home visits by a registered dietitian as intervention showed significant body weight gain in discharged patients, resulting in significant endpoint differences of 1.4–1.8 kg (~2–3% of body weight) between intervention and control [14, 15], although these studies were shorter in length (12 weeks) and did not deliver food items. Recent review articles on the efficacy of ONS, MOW and dietary advice [9, 37, 40, 41] to increase dietary intake and body weight yielded results in the range of 200–400 kcal/d and 0.6–1.5 kg (~1.5-2% of body weight), respectively. Although significant, the effect sizes were small and possibly, long-term compliance to, e.g., ONS or MOW, decreases over time and ONS might displace food rather than serve as an addition to regular dietary intake in the long run [42, 43].

Although it is difficult to accurately estimate body composition during a home visit, we employed various methods (hand-held BIA, upper arm- and calf circumference) to get insight into changes in lean body mass during the intervention. Results from the various measurements were consistent and data from BIA showed that weight loss in the control group was mainly due to loss of lean body mass, and weight gain in the intervention group was mainly due to an increase in lean body mass (and not body fat).

In the present study the nutrition intervention also had favourable effects on physical function, although we could not detect any changes in muscular strength. We found that both objectively measured physical function (SPPB) as well as subjectively experienced difficulties in walking improved only in the intervention group during the 6 months. In general, the evidence on the effects of nutrition intervention on physical function and muscular strength in older adults is limited. Although several studies using either MOW or ONS found effects on physical function [44, 45] and muscular strength [44], other studies did not (physical function: [46], muscular strength: [45, 47–49]).

In the present study, dietary intake at baseline was similar between groups at around 1500 kcal and 75 g protein per day which reflects the food provided by the hospital. Similar numbers have been previously reported by other investigators as well [50]. However, after discharge, the dietary intake decreased dramatically in the control group despite being informed at discharge of the importance of nutrition, while intake increased considerably in the intervention group. Interestingly, a low dietary intake nearly identical to the control group's intake was observed in a small pilot study in discharged hospital patients conducted by our research group in 2016 [19].

The results from our study are of potential public health importance for the following reasons: It is known that malnutrition is common in hospitalized older adults [1, 2, 51, 52] and unfortunately, our study demonstrates that weight loss continues after discharge in most participants who receive standard care, which has also been observed to some extent by other researchers [53]. Further, the treatment effects of our intervention, utilizing three components to improve nutritional status, were higher than reported from other studies having used only single modalities of nutrition intervention, e.g., ONS, MOW, or dietary advice [9, 40, 54–57]. It seems obvious that the wider approach of our nutrition therapy based on principles of NCP, in combination with the delivery of a variety of foods that were highly energetic and rich in protein while leaving space for individual needs and personal

Table 5. Dietary intake of the participants (baseline, endpoint), food related questions and food frequencies (endpoint).

Variables		Control ($n = 53$) Mean ± SD		Intervention ($n = 53$) Mean ± SD		*P*-value[a]
Energy intake (kcal)	baseline	1546 ± 297		1493 ± 360		0.412
	endpoint	731 ± 320		2412 ± 403		<0.001
Protein (g)	baseline	77.3 ± 14.8		74.7 ± 18.0		0.411
	endpoint	31.2 ± 15.5		118.2 ± 34.3		<0.001
Protein (g/kg BW[b])	baseline	1.1 ± 0.4		1.0 ± 0.3		0.202
	endpoint	0.4 ± 0.2		1.5 ± 0.4		<0.001
Carbohydrates (g)	baseline	135.3 ± 26.0		130.7 ± 31.5		0.411
	endpoint	77.2 ± 34.4		203.5 ± 43.0		<0.001
Fat (g)	baseline	77.3 ± 14.8		74.7 ± 18.1		0.412
	endpoint	31.1 ± 18.3		122.0 ± 29.8		<0.001
Dietary fibre (g)	baseline	22.7 ± 4.4		21.9 ± 5.3		0.413
	endpoint	6.4 ± 4.2		11.2 ± 3.8		<0.001
Do you enjoy food (endpoint)?	yes		73.6%		86.8%	0.088
Do you like the food that you get (endpoint)?	yes		77.4%		94.3%	0.012
How often do you eat a hot meal (endpoint)?	once or twice a week		11.3%		0.0%	0.003
	3-4 times a week		7.5%		0.0%	
	5-6 times a week		11.3%		1.9%	
	every day		67.9%		96.2%	
	more than once a day		1.9%		1.9%	
How often do you eat meat (endpoint)?	less than once a week		3.8%		0.0%	0.007
	once or twice a week		24.5%		3.8%	
	3-4 times a week		67.9%		88.7%	
	5-6 times a week		3.8%		7.5%	
How often do you eat vegetables (endpoint)?	never		3.8%		0.0%	0.101
	less than once a week		7.5%		3.8%	
	once or twice a week		22.6%		9.4%	
	3-4 times a week		26.4%		37.7%	
	5-6 times a week		7.5%		18.9%	
	every day		32.1%		30.2%	
How often do you eat fish (endpoint)?	less than once a week		7.5%		0.0%	0.096
	once or twice a week		22.6%		13.2%	
	3-4 times a week		66.0%		83.0%	
	5-6 times a week		3.8%		3.8%	
How much liquid do you drink (endpoint)?	one to two cups a day		3.8%		0.0%	0.014
	3-4 cups a day		18.9%		1.9%	
	5-6 cups a day		52.8%		66.0%	
	7 or more cups a day		24.5%		32.1%	
How much butter do you use on bread (endpoint)?	little butter		9.4%		11.3%	0.093
	medium butter		60.4%		39.6%	
	thick butter		30.2%		49.1%	

[a]*P*-value for the differences between groups. Based on independent samples *t*-test for continuous variables and based on chi-square statistics for categorical variables.
[b]g/kg BW = daily protein intake in g/kg body weight.

preferences, resulted in high acceptance of the delivered foods even after 6 months, satisfactory dietary intake, and body weight gain.

The current intervention was successful in improving body weight and maintaining muscle mass in discharged patients. The subgroup analysis indicated that the treatment effects were similar between subgroups, except in the three BMI categories, where participants in the high BMI category gained less body weight than participants in the middle and low BMI categories, which simply reflects different aims of the nutrition therapy dependent on individual characteristics of the participants. In our opinion the success of our study can be attributed to (1) the individualized and frequent nutritional therapy performed by a dedicated clinical nutritionist, (2) the provision of food developed to be palatable for older adults, rich in energy and protein as well

as with the appropriate texture; and (3) the length of the intervention being 6 months leading to significant improvements in both nutritional status and physical function.

Strengths and limitations

It is a strength of the present study that it was a randomized, controlled trial with very low drop out and 100% delivery of the intended intervention in 52 of 53 participants. Although a study like this cannot be doubly blinded, it is of importance that the assessment of the main outcomes was single blinded. We think that both the time length (6 months) and the intensity of intervention (five visits, three phone calls and free home delivered food) were appropriate to be able to observe potential treatment effects.

There are several limitations to our study. One is the gender imbalance between the control and the intervention group. Despite this gender imbalance our adjusted and unadjusted outcomes reach the same conclusion; nearly all subjects in the control group lost weight while almost all in the intervention group gained or maintained their weight, which cannot be explained by sex alone. Also, with our sample size being 106, some imbalances in the baseline factors can be expected and the method used for randomization was valid. Another limitation was that as outcome measurements were conducted at the patients' homes, we were limited in the assessment of physical function, i.e., lacking a measurement of gait speed, as well as in the measurement of body composition, i.e., having to rely on hand-held BIA and circumference measurements. However, we still collected valuable information about both body composition and physical function from which we can draw solid conclusions.

CONCLUSION

Our study shows that the time after hospital discharge leads to weight loss and loss of muscle mass, a decrease in food intake, and a deterioration in nutritional status in most older adults receiving the current standard care in Iceland. However, a 6-month nutrition therapy provided by a clinical nutritionist, following the principles of NCP in combination with freely delivered supplemental energy- and protein-dense foods, has beneficial effects on body weight, physical function, dietary intake, and nutritional status. The treatment effects were consistent across subgroups of study participants.

DATA AVAILABILITY

Data described in the manuscript, code book, and analytic code are publicly and freely available without restriction at: [https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdataverse.harvard.edu%2Fdataset.xhtml%3FpersistentId%3Ddoi%3A10.7910%2FDVN%2F38X3LX&data=04%7C01%7Cbsb6%40hi.is%7C1e998a8333904a1087a008d9803f56dd%7C09fa5f0e211846568529677ed8fdbe78%7C0%7C0%7C637681831802708546%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=LJU6Bm%2F9up1VO8rsWUdMnf5d5WewkRQpRUzfpmr8GgM%3D&reserved=0].

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AUTHOR CONTRIBUTIONS

BSB, OGG, KS, AMB, PVJ, and AR designed research; BSB and AR conducted research; BSB and AR analysed data; BSB, OGG, KS, AMB, PVJ, TIH, and AR wrote paper; AR had primary responsibility for final content. All authors read and approved the final manuscript.

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COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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Paper II

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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 $\geq$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 $\geq$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).

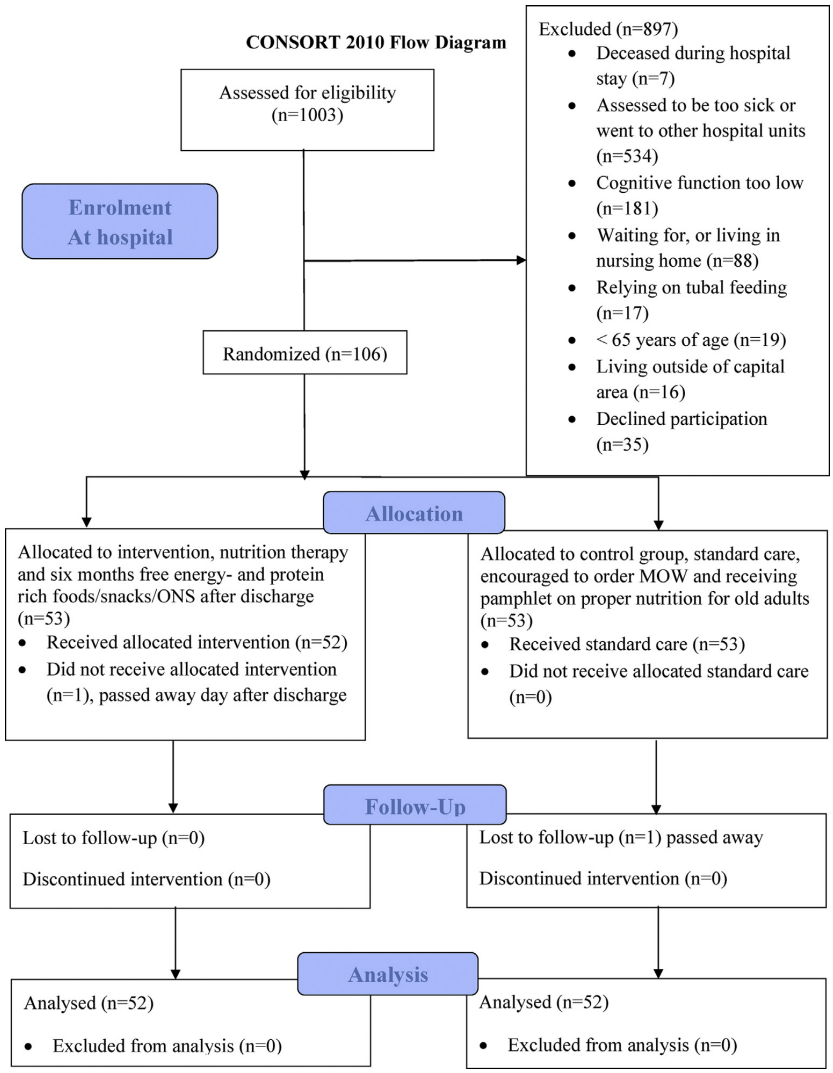

Fig. 1. Flow chart of the intervention study.

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 IOWA 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

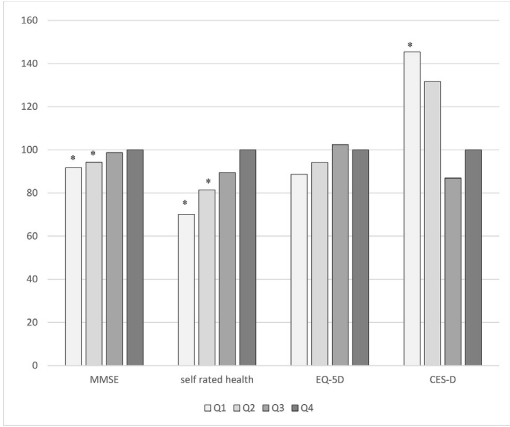

Fig. 2. Percentual differences in MMSE, EQ-5D, self-rated health and CES-D between participants categorized into body weight change quartiles at endpoint of the study. Based on general linear model - univariate. Adjusted for baseline values and sex. MMSE = Mini Mental State examination; CES = Centre 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 IOWA 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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Paper III

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Original Research

HOMEFOOD Randomised Trial – Six-Month Nutrition Therapy in Discharged Older Adults Reduces Hospital Readmissions and Length of Stay at Hospital Up to 18 Months of Follow-Up

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Abstract

BACKGROUND: Malnutrition is frequently observed in older adults and is associated with hospital readmissions, length of stay (LOS), and mortality in discharged patients.

OBJECTIVE: The aim of this study was to investigate effects of six-month nutrition therapy on hospital readmissions, LOS, mortality and need for long-term care residence 1-, 6-, 12- and 18-months post-discharge in older Icelandic adults.

DESIGN: Secondary analysis of a randomized controlled trial.

PaARTICIPANTS: Participants (>65 years) were randomised into intervention (n=53) and control (n=53) before discharge from a geriatric unit.

INTERVENTION: The intervention group received nutrition therapy based on the Nutrition Care Process, including home visits, phone calls, freely delivered energy- and protein-rich foods and supplements for six months after hospital discharge.

MEASUREMENTS: The Icelandic electronic hospital registry was accessed to gain information on emergency room visits (ER), hospital readmissions, LOS, mortality and need for long-term care residence.

RESULTS: The intervention group had a lower proportion of participants with at least one readmission compared to control (1 month: 1.9% vs 15.8%, P=0.033; 6 months: 25.0% vs 46.2%, P=0.021; 12 months: 38.5% vs 55.8%, P=0.051; and 18 months: 51.9% vs 65.4%, P=0.107). There was also a lower total number of readmissions per participant (1 month: 0.02 vs 0.19, P=0.015; 6 month: 0.33 vs 0.77, P=0.014; 0.62 vs 1.12, P=0.044) and a shorter LOS (1 month: 0.02 vs 0.92, P=0.013; 6 months: 2.44 vs 13.21; P=0.006; 12 months: 5.83 vs 19.40, P=0.034; 18 months: 10.42 vs 26.00, P=0.033) in the intervention group. However, there were no differences between groups in ER visits, mortality and need for long-term care residence.

CONCLUSION: A six-month nutrition therapy in older Icelandic adults discharged from hospital reduced hospital readmissions and shortens LOS at the hospital up to 18-months post-discharge. However, it did neither affect mortality, ER, nor need of long-term care residence in this group.

Key words: Nutrition status, oral nutrition supplements, readmission, mortality.

Introduction

Malnutrition is a frequently observed problem in older adults in hospitals and it has been reported that nutrition status often continues to decline during the stay in the hospital, resulting into a high proportion of older adults who are malnourished when discharged home (1-3). Malnutrition has many negative consequences, such as a reduction in body weight and a worsening of physical function, both associated with a loss of independence (4, 5). These unfavourable condition in older adults is also related to increased odds of hospital readmissions and mortality (6-8).

The time after hospital discharge can represent an opportunity for dietary intervention in older malnourished patients (9). It is vital to test whether a dietary intervention that increases energy- and protein intake to reduce risk of malnutrition is effective in preventing hospital readmissions, shortening the length of stay (LOS) once admitted, decreasing risk of mortality, and lessening the need for long-term care residence in discharged older adults.

A recently published meta-analysis (10) on this topic included nutrition trials which investigated personal dietary counselling with a focus on everyday food items (11, 12), oral nutritional supplements (ONS) (13, 14), or a mix of food and ONS (15, 16) to reach appropriate intake levels of energy and protein. And according to this meta-analysis, older discharged and hospitalized patients who received such intervention experienced a 16% lower risk of readmission in contrast to older adults having received standard care (10). The follow-up time in the included studies ranged from 30 to 90 days post-discharge, and hence some of the studies had quite a short duration compared to what is recommended by the European Society of Clinical Nutrition and Metabolism (ESPEN) (9). Further, this meta-analysis (10) did not consider LOS during readmissions or emergency room (ER) visits.

Another systematic review and meta-analysis that assessed nutritional therapy during and after hospital stay on mortality in adult patients reported an effect on increased survival (17). The authors, however noted that more studies are needed to confirm those findings (17). Beneficial effects of protein supplementation on mortality have also been noted in some

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studies (18).

It has been shown that malnutrition increases the risk of nursing home admission (19), however, little is known about whether nutrition intervention in malnourished older adults can prevent need for long term care residence. To address this data gap in we conducted this secondary analysis of a randomised dietary intervention trial in older adults that were at nutritional risk after being discharged from hospital (20, 21). The aim of the present study was to investigate the effects of six-month nutrition therapy on hospital readmissions, LOS, risk for long-term care residence and mortality 1-, 6-, 12- and 18 months post-discharge in older Icelandic adults.

Materials and Methods

Study design

The HOMEFOOD study was a randomised controlled six-month intervention trial examining the effects of intense nutritional therapy, including free access to energy- and protein-dense foods delivered to subjects, on older adults that were at nutritional risk after being discharged to home from hospital. The trial was assessor blinded. The main outcome of this analysis was hospital readmissions (number of total readmissions, % of participants re-admitted, length of stay during readmissions) 1 months, 6 months, 12 months, and 18 months post-discharge. Additional outcomes were risk for long-term care residence and mortality. The study was conducted in Reykjavik, Iceland, starting in January 2019 and ending with the last participant receiving intervention in July 2020. This was a secondary analysis of the HOMEFOOD trial. The primary outcomes of the original study were body weight and physical function (20, 21).

Reporting, approval, and funding

The conduction and reporting of this trial followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for Randomized Trials of Nonpharmacologic Treatments (22). The Ethics Committee for Health Research of the National University Hospital of Iceland and data protection registry (24/2018) approved the study in August 2018 and was performed in agreement with the ethical standards laid down in the 1964 Declaration of Helsinki (23). Registration of the study was done and is accessible at clinicaltrials.gov (NCT03995303).

Setting and recruitment

Screening and recruitment of the participants took place at the Icelandic National Hospital in Reykjavik, Iceland, starting in January 2019 and ending in January 2020. This was carried out by a clinical nutritionist, in cooperation with the nurses of the geriatric hospital wards, from January 2019 to January 2020. Inclusion criteria were as follows: community dwelling in the Capital area; discharge home from the hospital within a day of recruitment; age ≥ 65 years; at risk for malnutrition according to the validated Icelandic Nutrition Screening Tool (24); agreeing to participate in the trial by giving written informed consent. Exclusion criteria were: cognitive impairment (measured as Mini-Mental State Examination (MMSE) score < 20 (taken within three months of recruitment) (25); tubal feeding; known dietary allergies/being on a special diet; severe chronic kidney disease (glomerular filtration rate < 30 mL/min/1.73 m^2); active cancer treatment; and not being able to communicate with the research team.

Randomisation

The principal investigator (AR) assigned all participants randomly (allocation ratio = 1:1) to either the intervention- or the control group. The Statistical Package for the Social Sciences (SPSS, version 26.0, SPSS, Chicago, IL, USA) was used to generate the random numbers for allocation purposes, which were obscured from the clinical nutritionist enrolling and assigning the participants till the time of assignment.

Intervention

The clinical nutritionist provided the intervention group with nutrition therapy during five home visits (conducted the day after hospital discharge and at one, three, six, and twelve weeks from discharge). Additionally, the participants received three separate phone calls from the clinical nutritionist at weeks two, five, and nine after hospital discharge to encourage adherence to the nutrition therapy. The nutrition therapy followed the standards of the Nutrition Care Process (26), which entails assessing a patients nutritional status, diagnosing their nutritional problem/s, suggesting appropriate nutritional treatment, monitoring that the problem improves/resolves, and lastly, evaluating the treatment suggested. As many of the participants received support from family members, friends, relatives, or home-care staff, they were invited to be present during the home visits for added support (For more details see 20, 21).

During the first home visit, the focus was on educating the participant about the consequences of inadequate energy and protein intake and age-related changes that can affect the ability to meet their energy and protein needs sufficiently, they also were given Icelandic guidelines for frail or sick older adults (27). Other parts of the Nutrition Care Process were then followed, identifying any nutrition related problems, and a nutrition therapy suggestion was set up to resolve these problems. As the NCP is highly individualised, the nutritional needs and problems of each participant were identified and solutions were put in place, e.g., provision of ONS, or foods suggested to minimize digestive issues. This action was done to work towards a set goal, e.g., to stop weight- and muscle loss by increasing energy and protein intake, or to lessen number of times digestive pain is experienced. The participants also received, free of charge, energy- and protein-rich cooked traditional foods (at least one hot meal daily and two snacks; Supplemental table 1) and ONS. These were delivered, free of charge, once weekly for 24 weeks, by study staff that helped

the participants to put the food safely in the refrigerator and explained how to open the provided packages, how to heat up the meals safely, and how the meals should be stored.

Control group

At discharge from hospital, the control group was provided with information on proper nutrition for older adults (published in 2018 by the Icelandic Directorate of Health (27)) and was encouraged to order Meals on Wheels (MOW), as both recommendations reflect the current standard of care in Iceland when discharging older adults at risk of malnutrition. The control group did not receive any further nutritional care or service by the hospital, primary care sector and community. The participants in the control group did not receive dietary counselling or provision of food by the study team during the study period.

Data collection

Data on participants' diagnosis (according to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)), number of medications, and height was obtained from the Icelandic electronic hospital registry SAGA (TM software 3.1.39.9) at recruitment. Background socio-demographic variables were obtained using a background questionnaire, asking into matters regarding e.g., age, sex, whether receiving home care, smoking habits, alcohol habits, and level of education, these were taken at baseline (day of discharge in the hospital) and at endpoint in the participants' home. Outcome assessors were blinded as to the intervention status of the participant.

Nutritional risk

The Icelandic Nutrition Screening Tool (ISNST) was used to evaluate the nutritional risk of potential participants, as this is a validated screening tool recommended by the Icelandic Medical Directorate of Health (27, 28). The ISNST has seven questions, where the questions give zero, one, two, four, or five points, this results in a total score range from zero to 30 points, for our participants the total score range was from one to 30 as you get one point for being ≥ 65 years old. For older adults zero to two points represents low risk of malnutrition, three to four points some risk, and ≥ five points represents being at high risk of malnutrition.

Primary Outcomes

Hospital readmissions (1, 6, 12 and 18 months)

In the fall of 2021, the Icelandic electronic hospital registry SAGA (TM software 3.1.39.9) was accessed for each participant and information extracted on hospital readmissions (number of readmissions and LOS and visits to the emergency room (ER) (number of visits) at 1, 6 (= end of intervention), 12 and 18 months after hospital discharge.

Excluded as "readmissions" were elective admissions to part-time rehabilitation wards where participants came in one to three days a week from 10:00-15:00 to see various health-care workers for rehabilitative purposes.

Secondary Outcomes

Information on mortality and on need for long-term care residence were retrieved from the electronic hospital registry SAGA (TM software 3.1.39.9). Need for long-term care residence was estimated using the Nursing Home Pre-Admission Assessment (NHPAA) which is a professional assessment of the needs of individuals for long term care in in a nursing- or residential home. This is a standardized procedure that assesses among others health status, mental state, and skills in activities of daily living. The purpose of the NHPAA screening is to identify individuals in need for long-term care residence in a nursing- or residential home. NHPAA gives a more thorough and complete picture of the condition and needs of a patient and whether they truly need a nursing home admission. This thorough assessment is important as there is limited access to nursing homes in Iceland, with long waiting lists, making prioritisation for admissions important based on the patient's needs. The outcome of this assessment is dichotomous, i.e., positive (= need for long-term care residence) or negative (= no need for long-term care residence).

Additional measurements

Dietary intake (0 and 6 months)

Two twenty-four-hour-dietary-recalls (24HR) were used to assess the dietary intake (in particular energy and protein) of the participants, one was taken at baseline the day of discharge, and one at endpoint in the home of the participant. The 24HR is used to get an estimate of intakes of energy and energy-giving nutrients of an individual during a 24-hour period, usually from midnight to midnight, the day before the recall is taken (29). The nutrition calculation program ICEFOOD was used to enter the results from the 24HR to calculate the dietary intake of the participants (30, 31). ICEFOOD was chosen to calculate dietary intake as it based on the Icelandic database of the chemical composition of food (ISGEM) (30, 31).

Anthropometric measurements (0 and 6 months)

Using a calibrated bodyweight scale (model no. 708, Seca, Hamburg, Germany) the weight of the participants was measured, with them wearing only light underwear or clothing, at discharge and at the endpoint measure. Body mass index (BMI) was then calculated from the height obtained at the hospital registry SAGA and from the participants measured bodyweight (kg/m^2).

Physical function (0 and 6 months)

A shortened version of the Short Physical Performance Battery (SPPB) was utilized to evaluate physical function of the participants (32). The assessment of four-meter walk time (gait speed) could not be conducted as it was not feasible to carry it out at the participants' homes. The total combined score therefore changed accordingly and ranged from zero to eight points.

Cognitive function (0 and 6 months)

Cognitive function evaluation was performed using the MMSE, an eleven-question questionnaire frequently employed to screen for cognitive impairment (25).

Depressive symptoms (0 and 6 months)

A modified version of the Centre for Epidemiologic Studies Depression (CES-D) scale, called IOWA, was used to evaluate depressive symptoms of the participants (33).

Adverse events related to foods provided to the intervention group

During the intervention period, the clinical nutritionist assessed if any adverse events were reported by the participants of the intervention group due to the foods provided, e.g., stomach pain, change in bowels, or nausea. Assessment of potential adverse events related to dietary intake is part of the NCP and standardized questions were used for this assessment.

Sample size

A priori sample size considerations in the HOMEFOOD study were based on the original aim of the study which was to investigate the effects of nutrition therapy on body weight and body composition in older adults after discharge from geriatric hospital wards. Building on our previous studies that focused on body weight change (34, 35), calculations suggested that a sample size of n = 44 in each group were sufficient for a 1.8 ± 3.0 kg difference between the groups to be statistically significant ($\alpha = 0.05$, $\beta = 0.8$). However, no sample size was calculated to detect a difference between the groups in relation to the primary outcome in the study reported in this article.

Statistical analysis

Analysing the data was done by using the statistical software (SPSS, version 26.0, SPSS, Chicago, IL, USA). Data variables were checked for normality using the Kolmogorov-Smirnov test. Data is presented as mean ± standard deviation (SD).

The calculation of differences between the groups at baseline were done by using independent samples' t-test (for normally distributed variables) or Mann-Whitney-U test (for not normally distributed variables) and for categorical variables the chi-square test was used.

A general linear model adjusted for baseline values and sex was used to investigate differences in physical variables, psychological outcomes, and dietary intake between the groups at endpoint. For continuous outcomes the results are shown as parameter estimates with 95% confidence intervals (95%CI) reflecting the mean adjusted differences in the outcome variables between groups.

A Mann-Whitney-U test was used to compare differences between the two groups in hospital readmissions, LOS, and ER visits at 1, 6, 12 and 18 months after discharge from hospital. The percentages of patients in the control- and in the intervention groups with at least one hospital admission and/or at least one ER visit during the study period were compared using gender adjusted logistic regression analysis.

Cox regression analysis adjusted for gender was used to investigate differences in mortality and NHPAA between groups. The underlying time scale was the time from the start of the intervention until event or month 18 post-discharge. Results are shown as hazard ratios.

Per-protocol analysis reflects endpoint calculations, as the dropouts were only included in baseline analysis and in the analysis on mortality. The level of significance was set at $P < 0.05$.

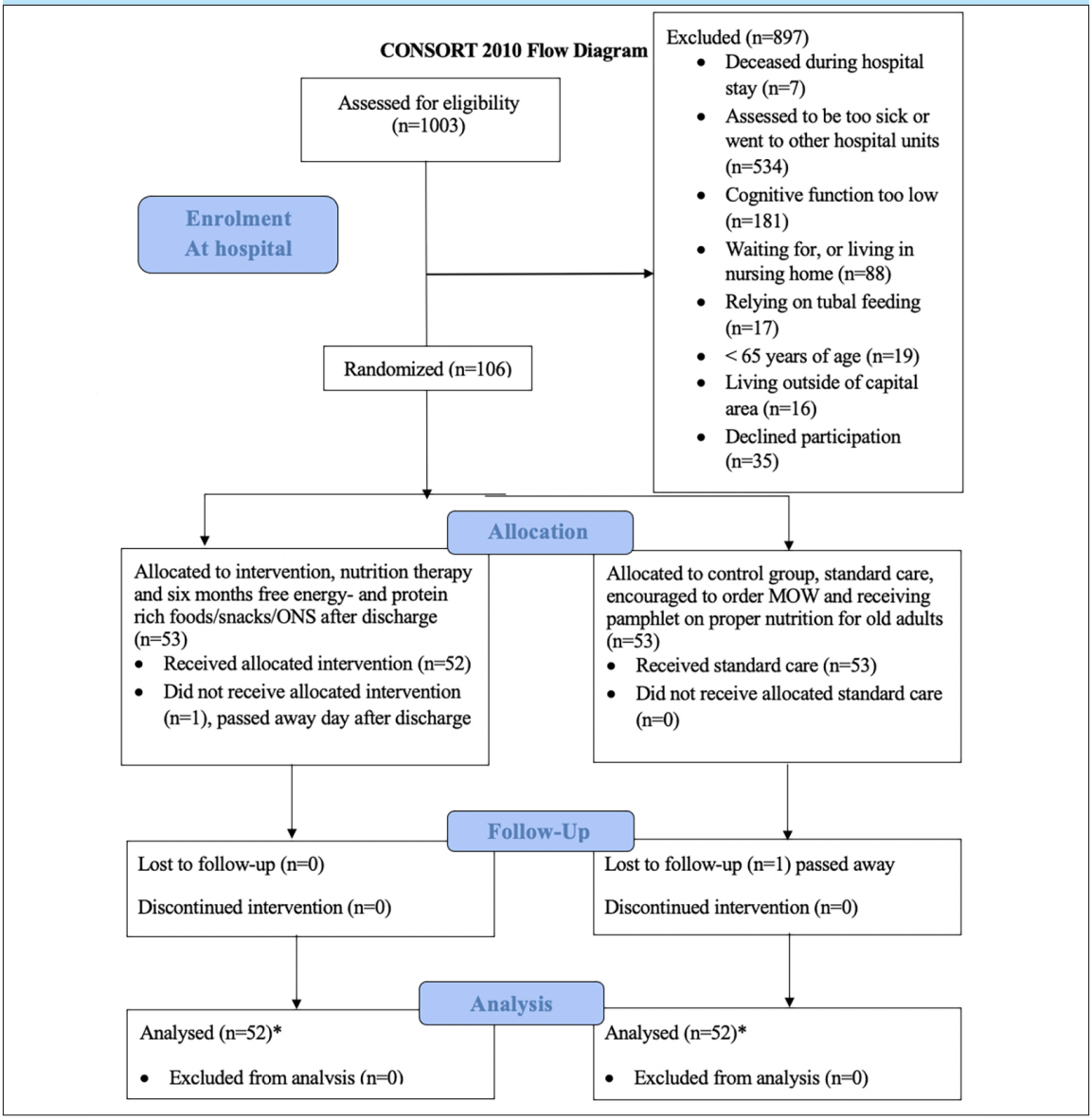
Results

The recruitment process from screening to analysis is shown in Figure 1. One thousand and three potential participants were screened and 897 were excluded as they did not meet the inclusion criteria, ending with 106 participants being randomised and participated in the study. One participant from each group dropped out during the trial (Figure 1). As the trial started, all participants of the intervention group, except for one (the drop-out), received the nutrition intervention from the clinical nutritionist, and the freely delivered energy and protein rich foods, snacks, and ONS. No adverse events related to the food provided were reported within the intervention group, i.e., nausea, a change in bowel movements, or other gastric issues.

Baseline characteristics are shown in Table 1. There was a higher percentage of women (71.7 vs 52.8%, P = 0.045) and a higher ISNST score (5.1 ± 1.7 vs 4.5 ± 1.3, P = 0.047) in the intervention group compared to the control group. No other baseline variables were significantly different between the two groups.

The intervention group experienced terms significant weight gain during the intervention period (1.7 kg ± 2.5 kg; which equals approximately 2% of body weight, only 1 out of 53 individuals lost > 1 kg body weight), while significant weight loss was observed among controls (-3.5 ± 3.9 kg; which equals approximately 5% of body weight, 42 out of 53 individuals lost > 1 kg body weight). After adjustment for sex (Table 2) this corresponded to 5.2 kg (95% CI: 3.9, 6.4) higher body weight in the intervention group at endpoint compared to controls. The intervention was also successful in increasing the participants' energy- and protein intake, improving their physical- and cognitive function, and their depressive symptoms in comparison to the control group as can be seen in Table 2. These results have been reported in more detail elsewhere (20, 21).

Figure 1. Flow chart



Baseline table and mortality analysis include all 106 participants

The number of ER visits, number of readmissions, LOS, and the proportion of subjects with at least one readmission at 1, 6, 12 and 18 months after initial hospital discharge are shown in Table 3. Overall, the intervention group had significantly fewer readmissions (significant at 1, 6 and 12 months) and shorter LOS (significant at all time points) when compared to the control group, however, the differences in ER visits were not significant. Similar results are yielded when comparing the proportion of participants with at least one hospital admission during the study period.

During the study- and follow up period, 23.1% in the control group and 13.5% in the intervention group had a positive NHPAA result which was not significant according to Cox regression analysis (intervention vs. control group: HR = 0.54 (95%CI: 0.21-1.38, P = 0.20).

In both groups, 9.4% of the participants deceased during

Table 1. Baseline characteristics of the participants

Variables	Control (n = 53) mean ± SD	Intervention (n = 53) mean ± SD	P-value*
Age (years)	81.8 ± 6.0	83.3 ± 6.7	0.228
Female (%)	52.8	71.7	0.045
Higher education (yes in %)	66	69.8	0.677
Lives alone (%)	66	66	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
ISNST (score)	4.5 ± 1.3	5.1 ± 1.7	0.047
ICD10 diagnoses	10.5 ± 3.8	10.3 ± 4.9	0.877
Medications	12.4 ± 4.2	12.2 ± 5.8	0.893
MMSE (score)	25.9 ± 2.9	26.1 ± 2.8	0.702
CES - depression scale (score)	5.6 ± 4.7	5.4 ± 4.2	0.861
Energy intake (kcal)	1543 ± 299	1490 ± 363	0.410
Protein (g)	77 ± 15	74 ± 18	0.411
Protein (g/kg BW**)	1.07 ± 0.36	0.99 ± 0.31	0.228

*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. SPPB = Short Physical Performance Battery Test, score range: 0-8; ISNST = Icelandic Nutrition Screening Tool sore range: 1-30, 1-2 = no nutritional risk, 3-4 = some nutritional risk, ≥ 5 = high nutritional risk; MMSE = Mini Mental State examination, score range: 0-30; ICD-10 = International Classification of Diseases, version 10; BMI = body mass index; CES-D= Centre of Epidemiological Studies depression IOWA scale, score range 0-22, > 9 = presence of depressive symptoms.
** Body weight

Table 2. Differences in outcomes between the groups at endpoint*

Outcome variable at endpoint	groups	estimate	95% CI		P-value
Body weight (kg)	control vs. intervention	-5.2	-6.5	-3.9	<0.001
Body mass index (kg/m2)	control vs. intervention	-1.8	-2.3	-1.3	<0.001
SPPB (score)	control vs. intervention	-1.0	-1.8	-0.3	0.007
MMSE (score)	control vs. intervention	-1.7	-2.6	-0.8	<0.001
CES - Depression (score)	control vs. intervention	3.1	1.6	4.5	<0.001
Energy intake (kcal)	control vs. intervention	-1696	-1834	-1557	<0.001
Protein (g)	control vs. intervention	-88	-98	-77	<0.001
Protein (g/kg BW**)	control vs. intervention	-1.1	-1.2	-1.0	<0.001

*Based on general linear model - univariate. Adjusted for baseline values and sex; SPPB = Short Physical Performance Battery Test, score range: 0-8; MMSE = Mini Mental State examination, score range 0-30; CES-D= Centre of Epidemiological Studies depression IOWA scale, score range 0-22, > 9 = presence of depressive symptoms; Control n = 52; intervention n = 52; ** Body weight

the study and follow-up period. Also, for this outcome, gender adjusted Cox regression analysis did not show any differences (intervention vs. control group: HR = 0.97 (95%CI: 0.28-3.34, P = 0.96).

Discussion

The present study was a secondary analysis of a six-month randomised controlled trial (20, 21) investigating the effects of nutrition therapy on hospital readmissions, LOS, mortality and need for long-term care residence 1-, 6-, 12- and 18 months post-discharge. Considering that the intervention had significant effects on energy intake, BMI, physical- and cognitive function as well as on depressive symptoms (20, 21), we also found that it reduced the number of readmissions, the proportion of subjects with at least one readmission, as well as LOS up to 18 months after discharge. However, the intervention did not affect ER visits, NHPAA results, or mortality.

Table 3. Hospital readmissions, ER room visits and LOS in the control- and in the intervention group during the study period

	control (n = 52)				intervention (n = 52)				
	mean	25th per.	median	75th per.	mean	25th per.	median	75th per.	P-value
No. of emergency room visits 1 month	0.21	0.00	0.00	0.00	0.12	0.00	0.00	0.00	0.370
No. of emergency room visits 6 months	0.98	0.00	0.00	2.00	0.79	0.00	0.00	1.00	0.750
No. of emergency room visits 12 months	1.69	0.00	1.00	2.00	1.4	0.00	1.00	2.00	0.911
No. of emergency room visits 18 months	2.31	0.00	2.00	2.75	1.96	0.00	1.00	3.00	0.928
No. of re-admissions 1 month	0.19	0.00	0.00	0.00	0.02	0.00	0.00	0.00	0.015
No. of re-admissions 6 month	0.77	0.00	0.00	1.00	0.33	0.00	0.00	0.75	0.014
No. of re-admissions 12 month	1.12	0.00	1.00	2.00	0.62	0.00	0.00	1.00	0.044
No. of re-admissions 18 month	1.52	0.00	1.00	2.00	0.92	0.00	1.00	1.75	0.072
Length of stay 1 month	0.92	0.00	0.00	0.00	0.02	0.00	0.00	0.00	0.013
Length of stay 6 months	13.21	0.00	0.00	13.75	2.44	0.00	0.00	1.50	0.006
Length of stay 12 months	19.40	0.00	3.00	21.00	5.83	0.00	0.00	7.75	0.034
Length of stay 18 months	26.00	0.00	9.00	39.25	10.42	0.00	2.00	10.75	0.033
Proportion of participants readmitted 1 months	15.8				1.9				0.033
Proportion of participants readmitted 6 months	46.2				25.0				0.021
Proportion of participants readmitted 12 months	55.8				38.5				0.051
Proportion of participants readmitted 18 months	65.4				51.9				0.107

*P-values for the differences between groups in emergency room visits, no. of readmission and length of stay are based on Mann-Whitney U test. P-values for the differences between groups in proportion of participants readmitted are based on gender adjusted logistic regression; 25th per. = 25% percentile, 75th per. = 75% percentile. LOS = length of stay.

Hospital readmissions

Hospital readmissions are an important outcome in health sciences as they can negatively impact both an individual and the society (36). For an older adult, hospital readmissions in older persons are related to poor nutrition status, reduced health, physical dependence, decreased quality of life (37, 38), and increase in healthcare costs (39). It is of importance to test potential interventions which can reduce hospital readmissions (40). According to a recent systematic review by Lærum-Onsager et al. (2021), nutrition therapy in discharged patients resulted into a 16% lower risk of readmissions (10). Depending on the time point, our intervention resulted in a risk reduction (relative risk) of readmission between 21-88%, and its effects partly faded at later time points of the 18 months study period. This is not entirely unexpected considering the intervention period was six months, but the study period was 18 months. Lærum-Onsager et al. (2021) did not include LOS and not ER visits in their meta-analysis (10). We found significant effects of the nutrition intervention on LOS at all investigated time points, but the intervention did not affect ER visits.

Our intervention was intense and long and improved the participants' diet as well as their physical and mental health (20, 21), all of which can possibly explain the reduced readmissions in our study.

The age of the participants in our and the above-mentioned studies was similar (11-16), as was the number of medications and number of diseases (16). However, in our study, the control group had readmission rates (19% at 1 months and around 77% at 6 months according to Table 3) higher than reported in other studies (11, 14-16), which might indicate that home care assistance in Iceland is limited compared to other countries thus resulting into more frequent readmissions.

Mortality and need of long-term care residency

Besides hospital readmissions, the current study also investigated other important outcomes, i.e., risk of long-term care residence (NHPAA results) and mortality. The mortality rates were not significantly different between intervention and controls. This contrasts with findings from one meta-analysis which found a 37% mortality risk reduction based on the results from 13 intervention studies, comparable to the nutrition intervention described in our study (17). The mortality rate of 9.4% in our study was well within the range of mortality rates reported in the above-mentioned meta-analysis of 0.9 – 34.2%. Another systematic review and meta-analysis from the same study group (18) showed similar risk reductions and indicated clinical potential for multifaceted, individualized, high protein nutrition therapies.

Malnutrition has been associated with an increased risk of nursing home admission (19), but it is currently not known whether nutrition therapy in malnourished older adults can prevent nursing home admission. In our study, the percentage of positive NHPAA results, a tool that assesses the need for long-term care residence, in the control group seemed to be higher than in the intervention group although not statistically significant. Malnutrition can be linked to a higher risk of need for long term care due to its associations with, e.g., low physical function (41) and poor ADLs (42), low cognitive function (43) and increased depressive symptoms (44).

Finally, it is an important question to discuss how generalizable the results from this study are because the included study population presents only a fraction of the screened population.

The two main reasons for exclusion from study participation

were 1) low cognitive function according to MMSE (n=181), and 2) being too sick or being discharged to other hospital units where we did not have permission to recruit (n=534). Low cognitive function as an exclusion criterion is used in study design and is required by the ethical committee to protect the potential participant from an intervention which they cannot understand or follow. It is our opinion that in a real-life setting, our intervention would work independently from cognitive function if a care giver guided a participant with low cognitive function through the nutrition therapy. We also think that more vulnerable participants (exclusion reason 2) who were not discharged home but to another hospital ward might benefit from such intervention.

The dietary intervention in this study was conducted by the University of Iceland and demonstrated that nutrition therapy is beneficial for a wide array of outcomes in the investigated population of older adults at risk for malnutrition. The primary sector was not involved in this intervention; however, future involvement of the primary sector is considered of great importance for the aim of implementation of such intervention as standard care for older adults at risk for malnutrition.

Strengths and limitations

An apparent strength of the present study was that it was a randomised, controlled trial with a very low drop out and despite COVID-19 challenges during the end of the study a 100% delivery of the intended intervention to 52 of the 53 participants was achieved.

However, this study also has some limitations: in dietary intervention studies as this one, the participants cannot be blinded to the treatment given. The time length (six months), the intensity of the intervention (five nutrition therapy sessions delivered in the participant's home, three phone calls, and free home delivered food) and, importantly, the length of follow up made this study one of the most extensive studies in the field of nutrition therapy in older discharged older adults. It is however clear, that such intense study protocol comes at the cost of the number of participants that can be included in such intervention. Our study was designed and adequately powered for the detection of anthropometric differences between the groups (20, 21). As shown by our own study as well as by the study from Lindegaard Pedersen et al 2017 (11), large differences in incidences (considering a categorical outcome) are necessary to detect significant differences between two groups in a study with limited sample size. Thus, lack of statistical power might be an explanation why the current study failed to detect a significant difference between the groups in the NHPAA results.

Conclusion

This study shows that a six-month nutrition therapy in older Icelandic adults discharged home from hospital reduces hospital readmissions and shortens LOS at the hospital up to 18-months post-discharge but did not affect mortality, ER visits, or need of long-term care residence in this group.

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Conflict of interest: Blondal BS: no conflict of interest. Geirsdottir OG: no conflict of interest. Halldorsson TI: no conflict of interest. Beck AM: no conflict of interest. Jonsson PV: no conflict of interest. Ramel A: no conflict of interest.

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Ethical standards' declaration: This study complied with the current laws of Iceland in which it was conducted.

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