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SCREENING FOR MALNUTRITION AND INTERVENTION WITH ORAL NUTRITIONAL SUPPLEMENTS IN NURSING HOME RESIDENTS

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ABSTRACT

Malnutrition in the elderly population is a common and known problem with serious consequences. The use of oral nutritional supplements as intervention option to improve the nutritional situation has also been investigated in various studies. However, data from the nursing home setting, and especially nutritional intervention studies in this special, often functionally impaired target group, are rare, also with regard to functional outcome. Key part of the present thesis is therefore an intervention trial with oral nutritional supplements (ONS) in six nursing homes in the area of Nuremberg-Fuerth.

First, it was aim to identify all residents with malnutrition or at risk of malnutrition during screening, which revealed a prevalence rate of 64% in all residents included. Furthermore, the application of different markers of nutritional risk allowed the comparison of MNA® (Mini Nutritional Assessment) with single risk markers (low BMI, low food intake, weight loss). It was shown that the MNA enabled broad identification of all residents at nutritional risk, covering 90.4% of subjects presenting one or more single nutritional risk markers. Moreover, the association between nutritional status and functionality was investigated. Impairment of cognition, mood and depression, and in particular severe impairment, was to a higher share present in residents at nutritional risk, independent of the chosen risk marker.

Objective of the subsequent randomized controlled intervention trial was to investigate the effects of ONS on nutritional status, functionality and quality of life of all residents affected from malnutrition or at risk of malnutrition. Since the consumption of high volumes poses a frequent problem for elderly persons, a novel low-volume nutrient- and energy-dense ONS was used in order to enhance compliance. Daily provision of 2x125ml ONS resulted in this group of mostly severe functionally impaired residents in a significant improvement of nutritional status compared to the control group with routine care. Functional outcome parameters did not show significant changes, however, assessment was often hampered by presence of dementia or immobility. This reduced the significance of results for functionality and concurrently highlights the need for better tools for this target group. Furthermore, there were indications for positive effects on quality of life, which require further research though.

The third objective of the present thesis was a detailed investigation of the compliance, which was 73% and indicated a good acceptance of the low volume ONS among participants. A high compliance (≥80%) resulted in significantly higher weight increases than a low compliance (≤30%) that markedly reduced the success of the intervention. Gastrointestinal complaints as well as depression and immobility were related to a lower compliance. In contrast, a poor nutritional status according to MNA and the presence of chewing difficulties was associated with a higher compliance. To enhance the efficacy of ONS it is particularly important to take these aspects into account.

ZUSAMMENFASSUNG

Mangelernährung ist ein häufiges, inzwischen bekanntes und gut untersuchtes Problem in der älteren Bevölkerung mit gravierenden Folgen. Auch der Einsatz von Trinknahrungen als Interventionsmöglichkeit zur Verbesserung der Ernährungssituation war bereits Gegenstand vielzähliger Studien, weniger gut ist jedoch die Datenlage im Pflegeheimbereich. Insbesondere Ernährungsinterventionsstudien in dieser speziellen, oft funktionell beeinträchtigten Zielgruppe, auch in Hinblick auf funktionelle Parameter, sind rar. Kernstück der vorliegenden Dissertation stellt somit eine Interventionsstudie mit Trinknahrung in sechs Pflegeheimen im Raum Nürnberg-Fürth dar.

Ziel war es zunächst im Rahmen eines Screenings all diejenigen Bewohner zu identifizieren, die eine Mangelernährung oder ein Risiko für Mangelernährung aufwiesen, was bei 64% der eingeschlossenen Bewohner zutraf. Die Anwendung unterschiedlicher Marker für Ernährungsrisiken erlaubte außerdem den Vergleich von MNA® (Mini Nutritional Assessment) mit einzelnen Risikomarkern (geringer BMI, geringe Nahrungsaufnahme, Gewichtsverlust) und es zeigte sich, dass der MNA eine breite Erfassung aller Bewohner mit einem Ernährungsrisiko ermöglichte und 90.4% der Bewohner mit einem oder mehreren der untersuchten Einzelmarker identifiziert wurden. Weiterhin wurde der Zusammenhang zwischen Ernährungsstatus und Funktionalität analysiert. Hierbei stellte sich heraus, dass Beeinträchtigungen von Kognition, Stimmung und Mobilität, und insbesondere schwere Formen, häufiger bei Bewohnern mit Ernährungsrisiko vorlagen, unabhängig von der Art des verwendeten Risikomarkers.

Die nachfolgende Interventionsstudie hatte zum Ziel, in randomisiert-kontrolliertem Design die Effekte von Trinknahrung auf den Ernährungszustand, die Funktionalität und Lebensqualität aller von Mangelernährung oder einem Risiko für Mangelernährung betroffenen Bewohner zu untersuchen. Da der Verzehr größerer Volumen ein häufiges Problem für ältere Personen darstellt, wurde eine neue kleinvolumige, energie- und nährstoffdichte Trinknahrung eingesetzt um die Compliance zu erhöhen. Die Gabe von täglich 2x125 ml Trinknahrung führte bei den älteren, überwiegend stark funktionell beeinträchtigten Bewohnern zu einer signifikanten Verbesserung des Ernährungszustandes im Vergleich zur Kontrollgruppe mit üblicher Versorgung. Bei den funktionellen Parametern zeigten sich keine signifikanten Veränderungen, allerdings wurde die Erfassung häufig durch das Vorliegen von Demenz oder Immobilität behindert. Dies limitierte die Aussagekraft der Ergebnisse zur Funktionalität und verdeutlicht gleichzeitig den Bedarf für geeignetere Erfassungsmethoden für diese Zielgruppe. Weiterhin wurden Anzeichen einer verbesserten Lebensqualität beobachtet, allerdings besteht hier weiterer Forschungsbedarf.

Das dritte Ziel der vorliegenden Dissertation war eine genaue Betrachtung der Compliance, welche im Mittel 73% betrug und eine gute Akzeptanz der kleinvolumigen Trinknahrung bei den Bewohnern widerspiegelt. Eine hohe Compliance (≥80%) führte zu signifikant höherer Gewichtssteigerung als eine geringe Compliance (≤30%), die den Interventionserfolg maßgeblich reduzierte. Sowohl gastrointestinale Beschwerden als auch Depression und Immobilität waren mit geringerer Compliance verbunden, hingegen gingen ein schlechter Ernährungszustand, gemessen mittels MNA, und das Vorliegen von Kaustörungen mit höherer Compliance einher. Um die Wirksamkeit von Trinknahrungen zu optimieren ist es besonders wichtig, diese Aspekte zu berücksichtigen.

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ADL	Activities of daily living
BMI	Body Mass Index
BW	Body weight
CC	Calf circumference
CG	Control group
d	Day
ESPEN	European Society for Clinical Nutrition and Metabolism
f	Female
GDS	Geriatric Depression Score
GIC	Gastrointestinal complaints
GS	Gait speed
HGS	Handgrip strength
IG	Intervention group
IQR	Interquartile range
ITT	Intention to treat
Kcal	Kilocalories
Kg	Kilogram
LI	Low food intake
m	Male
m^2	Square meter
min	Minutes
ml	Milliliter
MMSE	Mini Mental State Examination
MNA	Mini Nutritional Assessment
MNA-SF	Mini Nutritional Assessment Short-Form
n	Number
NH	Nursing home
n.s.	Not significant
ONS	Oral nutritional supplements
p	Points
PEG	Percutaneous endoscopy gastrostomy
Q	Quartile
r	Correlation coefficient
SD	Standard deviation
UAC	Upper arm circumference
QoL	Quality of life
WL	Weight loss
y	Years

CHAPTER I

GENERAL INTRODUCTION

Malnutrition in the elderly population is a multifaceted problem with severe consequences. With increasing age, various factors like loss of appetite, multimorbidity and impaired function may contribute to unintentional weight loss, the risk for malnutrition or even overt malnutrition.[1] This development often represents the entry point to a vicious cycle that is especially detrimental for elderly, leading to a number of negative health effects. These include increased susceptibility for infections, a higher rate of frailty which is often accompanied by falls, a concurrent loss of functionality, independence and quality of life, as well as higher mortality.[2-5] Even though malnutrition in elderly persons is a problem in different settings,[6] the following work will focus on nutritional risk among nursing home residents as the knowledge on this population is still limited.

To counteract deterioration of nutritional status in nursing home residents, it is important to early recognize nutritional risk and take appropriate measures.[7-9] Therefore, implementation of both screening for malnutrition and, as appropriate, subsequent assessment and initiation of nutritional treatment represent crucial steps which are prerequisite for improved nutritional care.[10] They might help reduce the number of residents affected by malnutrition and its detrimental consequences, which may also include a considerable economic burden for the institutions through malnutrition-related costs.[11] The consequences of malnutrition are well known, and there are many guidelines[12-14] and initiatives[15,16] in place that address the importance of screening and consequent nutritional management, including the use of oral nutritional supplements (ONS).[8,17] However, as malnutrition is still an issue in nursing homes, there seems to be a gap between the existence of guidelines and implementing these successfully into practice.

The reasons for this discrepancy are not completely clear, but apart from the factors time and costs, in practice uncertainty might exist about how to identify elderly nursing home residents at nutritional risk and in need of nutritional support.[12] Consensus on screening methodology has not been reached yet and the debate about the best way to identify nutritional risk in elderly is ongoing.[12,18,19] Despite existence of different single markers for malnutrition like low BMI, low intake or high unintentional weight loss, as well as composite screening tools like the MNA, that was specifically designed for older people, there is still no gold standard available. The above mentioned single nutritional risk markers allow easy identification of affected residents, but they may be misleading if considered in isolation.[17,20,21] In contrast, the more complex MNA not only evaluates various nutritional markers but also general health as well as psychological and functional aspects possibly contributing to nutritional risk.

Furthermore, it allows distinguishing between the malnourished and those at risk, which contributes to its preventive use, allowing early intervention.[22,23]

To enable broad identification of nutritional risk, it is interesting to find out if the MNA also identifies all subjects showing one of the above mentioned single markers of nutritional risk which are regarded as key elements for diagnosis of malnutrition.[18,19,24] This aspect has not been investigated so far. Moreover, there is only limited knowledge on the presence of functional impairment, including both physical and mental decline, in nursing home residents at nutritional risk compared to those not at risk, and research required.[25]

Further investigation of screening methodology and research on the relation between nutritional risk and functional impairment are not only relevant issues for nursing practice but also for the conduction and interpretation of future nutrition intervention trials in this setting for various reasons. First, information on these aspects might help to increase comparability of study results as it sheds more light on both the MNA and different single markers of nutritional risk which are available for screening. Secondly, it would also enable to evaluate the current practice of excluding residents with functional impairment, and in particular dementia, from trials, which might have an impact on generalizability of research results.[26]

To overcome nutritional deficiencies and the state of malnutrition, ONS are regarded an effective method. To date, different meta-analyses and reviews already reported the positive effects of oral nutritional supplementation with regard to energy and nutrient intake, nutritional status, complication rates and mortality in elderly.[4,27-30] However, evidence from nursing homes is still rare.[28,31] In particular, little is known on the effect of ONS on functional status and quality of life of institutionalized elderly. In a recent review investigating if improved body weight through different kinds of nutritional support in nursing home residents may translate into better functional outcomes such a concordance was found in three out of six studies.[31] This indicates a positive impact on functionality, however, the need for further research is high-lighted to draw significant conclusions.[28,31] Besides, it hast to be taken into account that results are seldom applicable for the entire nursing home population, as subjects with functional and cognitive impairment are often excluded from studies.[32-35]

Even though ONS are considered an effective way of nutritional therapy in elderly, and evidence based recommendations and guidelines support the early use of sip feeds in order to avoid or correct nutritional deficits in advanced age,[5,13,14] low compliance to oral nutritional support has been described as a practical problem.[36,37] The volume that needs to be consumed is a known barrier for ONS use among elderly, which leads to a reduced compliance and high product wastage.[38-40] Since the positive effects of ONS can only be achieved as a result of an increased nutrient intake, it is of particular interest to optimize compliance[41] and thereby the effectiveness of an intervention. To improve both compliance

and effectiveness of ONS, which is especially problematic if ONS need to be taken over a longer duration, the provision of reduced volumes with a higher nutrient- and energy-density might be one possible solution.[37,40,42-45] For this reason, the use of higher energy formula ONS has become more and more popular over time, and nowadays the high energy (1.5 kcal/ml) variants represent the most used option. Recently, an even more concentrated, low-volume ONS has been developed to overcome the problem of low compliance, however, only few reports using this ONS indicating a better compliance exist to date.[46-48] Evidence needs to be established about the efficacy to further clarify its possible beneficial impact.

To expand the knowledge on nutritional and functional status of this very old, often impaired nursing home population as well as the role of nutritional intervention with this particular low volume, nutrient- and energy-dense ONS, a nutrition intervention trial was conducted in the nursing home setting, which is described in chapters 2-4.

Chapter two evaluates the results of a screening for malnutrition in six nursing homes which were recruited for this study in the area of Nuremberg-Fuerth. All residents with malnutrition or at risk were identified by using both the MNA and single markers of nutritional risk, which also allowed a comparison of different screening parameters. Through concurrent assessment of functional parameters, it was possible to identify associations between the different nutritional risk markers and functional impairment. Investigation of these aspects was particularly relevant as it provided important information for the conduction and design of the subsequent, but also future intervention trials, especially with regard to baseline characteristics on nutritional and functional status of nursing home residents. For the nutrition intervention trial, with its findings described in chapter three, the intention was to first include all residents with malnutrition or at risk without missing any subject possibly in need of nutritional support, including those with cognitive and mobility impairment, and secondly also to focus on functional outcomes and well-being apart from nutritional parameters. To additionally address the problem of compliance with ONS and gain insights into a novel ONS variant, a low-volume nutrient-and energy-dense oral nutritional supplement was used for the study. Chapter four describes a detailed analysis of the observed compliance, its impact on the success of the intervention and the possible influencing factors on compliance with ONS in this setting.

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AIMS OF THE THESIS

The present thesis which describes the results of a study in nursing homes, consisting of a cross-sectional evaluation as well as an intervention trial, aims improving knowledge on both nutritional risk among nursing home residents and the possible benefits of an intervention with oral nutritional supplements in a challenging population of older people with high functional impairment. The thesis will specifically answer the questions outlined below per chapter.

CHAPTER II:

What is the current prevalence of malnutrition and its risk among German nursing home residents, and is the Mini Nutritional Assessment (MNA) able to identify all residents at nutritional risk according to the relevant single nutritional risk markers low BMI (≤22 m^2/kg), weight loss and low intake which are often used in current practice? Is there an association between presence of nutritional risk and functional impairment in nursing home residents?

CHAPTER III:

What are the effects of a nutritional intervention with a low-volume, nutrient- and energy-dense oral nutritional supplement (ONS) on nutritional status, functionality and quality of life of nursing home residents, including those with high cognitive and mobility impairment?

CHAPTER IV:

How compliant are nursing home residents with a low-volume, nutrient- and energy-dense ONS and what impact does the level of compliance have on the effectiveness of an intervention with ONS in this population? Which residents' characteristics are related to compliance?

CHAPTER II

PUBLICATION NO.1

SCREENING FOR MALNUTRITION IN NURSING HOME RESIDENTS: COMPARISON OF DIFFERENT RISK MARKERS AND THEIR ASSOCIATION TO FUNCTIONAL IMPAIRMENT

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Abstract

Objectives: To identify nursing home residents with malnutrition or at risk of malnutrition by using different markers, determine if the Mini Nutritional Assessment (MNA®) is able to identify all residents at risk according to single risk markers and explore the relation between risk markers and functional impairment.

Design: Cross-sectional study.

Setting: Six German nursing homes.

Participants: 286 residents (86±7y, 89% female).

Measurements: Screening for malnutrition or its risk included low BMI (≤22 kg/m²), recent weight loss (WL), low food intake (LI) as single risk markers and MNA (<24 points, p.) as composite marker. Prevalence of single nutritional risk markers in different MNA categories was compared by cross-tables. Mental (cognition, mood) and physical function (mobility) were assessed by interviewing nursing staff and association of impaired status to nutritional risk markers determined by Chi² test.

Results: 32.9% of residents had a low BMI, 11.9% WL and 21.3% LI. 60.2% were categorized malnourished (18.2%) or at risk of malnutrition (42.0%) by MNA. 64% presented at least one of these nutritional risk markers. Of those classified malnourished by MNA, 96.2% also showed low BMI, WL or LI. In contrast, eleven residents (9.6%) considered well-nourished by MNA presented single risk markers (9 low BMI, 2 WL). Cognitive impairment, depressive symptoms and immobility was present in 59.0%, 20.8% and 25.5%, respectively. Functional impairment, and in particular severe impairment, was to a higher proportion present in residents at nutritional risk independent of the chosen marker (MNA<24 p., low BMI, WL, LI).

Conclusion: The high prevalence of nutritional risk highlights the importance of regular screening of nursing home residents. The MNA identified nearly all residents with low BMI, WL and LI. The close association between nutritional risk and functional impairment requires increased awareness for nutritional problems especially in functionally impaired residents, to early initiate nutritional measures and thus, prevent further nutritional and functional deterioration.

Keywords: Screening, malnutrition, nursing home, functionality, nutritional risk, MNA

Introduction

Screening for malnutrition in nursing homes is a crucial first step to early identify affected residents and those at risk that should be followed by nutritional assessment and initiation of appropriate nutritional treatment.[1-3] Despite the detrimental effects of malnutrition,[4,5] guidelines[6-8] and proven efficacy of oral nutritional supplements (ONS),[9] this is, however, not always common practice. Consequences of malnutrition include adverse health effects like infections, complications, prolonged hospital stays and mortality, but also loss of independency and quality of life.[1,10,11] Besides, the costs resulting from malnutrition[12] may lead to considerable economic burden for nursing homes, enhanced by the rising demand of an aging population.[13]

Lack of regular nutritional screening might reflect uncertainty about how to identify elderly subjects in need of nutritional support in daily routine.[6] Low BMI, weight loss and low food intake are regarded key elements for diagnosis of malnutrition or nutritional risk, indicating the need for in-depth nutritional assessment.[14-16] Although consideration of these easily identifiable single markers in isolation can be misleading, they are often used as stand-alone parameters to judge nutritional status.[3,15,17] Alternatively, the Mini Nutritional Assessment (MNA®) represents a composite screening tool specifically designed and recommended for older people. It evaluates nutritional markers and general health aspects, but also includes psychological and functional items contributing to malnutrition development. Distinguishing between malnourished and those at risk, it is of preventive use allowing early intervention.[18,19] However, it is not known if the relatively complex MNA identifies all nursing home residents showing one or more of the above mentioned single markers of malnutrition, requiring intervention if present. To date, debate about the best way to identify elderly persons at nutritional risk is ongoing.[6,15,17]

Apart from nutritional problems, older people often suffer from functional decline. The MNA links functional impairment to nutritional risk, but data on the presence of both physical and mental impairment in nursing home residents with or without nutritional risk is limited and research on this association required.[20]

Both lack of consensus on screening methodology and limited knowledge on the relation between nutritional risk and functional impairment are not only relevant for nursing practice, but also for future nutrition intervention trials and their interpretation, as comparability is limited and functional impairment is commonly regarded an exclusion criterion.

Thus, the objectives of the study were (i) to identify nursing home residents with malnutrition or at risk of malnutrition using different markers, (ii) to determine if the MNA is able to identify all residents at risk according to other markers and (iii) to explore the relation between risk markers and functional impairment.

Methods

Study design

This cross-sectional study forms part of an intervention trial investigating the effects of oral nutritional supplements (ONS) on nutritional and functional status in nursing home residents with malnutrition or at risk of malnutrition.

All residents from six nursing homes in Nuremberg and Fuerth, Germany, meeting the following inclusion criteria, or their legal proxies, were asked for written informed consent: age >65 years, long-term care, no end-stage disease, no hospital stay, no tube-feeding, no dialysis or intolerance to ONS.

Ethical approval was obtained from the ethics committee of the Friedrich-Alexander-Universität Erlangen-Nürnberg, Germany. Between March and December 2009 trained research staff assessed residents´ characteristics, nutritional and functional status in cooperation with the responsible qualified nurses.

Residents' characteristics

Information on gender, age, care level according to the German nursing insurance system (0= <45, 1= 45-<120, 2= 120-<240, 3= ≥240 min need of basic care/day), eating dependency during meal times (independent, partly dependent, completely dependent) and current provision of nutritional support, either ONS or home-made snacks, were collected from residents' files.

Nutritional risk

Screening for malnutrition included the following nutritional risk markers:

Body mass index (BMI) was calculated as weight (kg)/ height² (m^2) using height and current weight from residents' files, with BMI ≤22 kg/m^2 defined as low.

Weight loss (WL) was considered if it was unintended and amounting >5% in the last 3 or >10% in the last 6 months, calculated from weight history of routine documentation.

Low intake (LI) was reported by nursing staff, if food intake was involuntarily remarkable low during the last week.

MNA® *(*Mini Nutritional Assessment) was completed in personal interviews with nurses. Weighted answers of this standardized 18-item-questionnaire covering anthropometry, global assessment, dietary patterns and subjective assessment sum up to a maximum score of 30 points (p.). A total score ≥24 p. indicates normal nutritional status, 17-23.5 p. risk of malnutrition and <17 p. malnutrition.

Nutritional risk was defined as presence of at least one of these 4 nutritional risk markers.

Functional status

Cognitive impairment and **depressive mood** (mental function) were assessed in standardized interviews with the responsible nurses who subjectively classified into no, moderate or severe impairment.

Mobility impairment (physical function) was regarded absent if residents were able to move independently ≥3m with or without walking aid (including wheelchair), moderate if independent movement was not possible (immobile sitting) and severe if bedridden.

Data analysis and statistics

The statistical analysis was performed using SPSS (19.0). Categorical variables are presented as absolute numbers and percentages, continuous variables as mean and standard deviation (SD). Cross-tables are used to compare prevalence of low BMI, WL and LI in different MNA categories. Chi-square tests were performed to identify differences in the distribution of residents´ characteristics between residents with and without nutritional risk and to investigate associations between nutritional and functional status. *P*-values <0.05 were considered statistically significant.

Results

Residents' characteristics

From a total of 565 nursing home residents, 31 did not meet inclusion criteria. Informed consent was obtained for 286 residents (participation rate 53.6%). Mean age of participants was 86±6.8 years, 88.8% were female. Eighty per cent required ≥45 minutes basic care daily and 49.3% were eating-dependent. Mean BMI was 24.8±4.6 kg/m². General characteristics, stratified for presence of nutritional risk, are summarized in table 1. Residents at risk were more often female ($p<0.05$), in higher need of care ($p<0.001$) and more dependent during mealtimes ($p<0.001$). Twenty-five residents (13.7%) at nutritional risk received oral nutritional support.

Table 1: Characteristics of residents with (n=183) and without (n=103) nutritional risk[1]

		nutritional risk		no nutritional risk		
		n	%	n	%	
Gender	male	15	8.2	17	16.5	*
	female	168	91.8	86	83.5	
Age (years)	65 - 74	14	7.7	7	6.8	
	75 - 84	46	25.1	30	29.1	
	85 - 94	104	56.8	54	52.4	
	95+	19	10.4	12	11.7	
Level of care	0 (<45 min basic care)	24	13.1	33	32.0	***
	1 (45- <120 min)	41	22.4	44	42.7	
	2 (120- <240 min)	66	36.1	24	23.3	
	3 (≥240 min)	52	28.4	2	1.9	
Eating dependency	independent	56	30.6	89	84.6	***
	partly dependent	68	37.2	12	11.7	
	completely dependent	59	32.2	2	1.9	
Oral Nutritonal Support	no	158	86.3	103	100.0	***
	oral nutritional supplements	18	9.8	0	0.0	
	home-made snacks	7	3.8	0	0.0	

Chi-square test *$p<0.05$, *** $p<0.001$

MNA: Mini Nutritional Assessment

[1]nutritional risk defined as presence of MNA≤23.5 p., BMI ≤22 kg/m², weight loss (>5/10% in last 3/6 months) or low food intake

Nutritional risk

One third (32.9%) of the participants had a low BMI, LI was reported in 21.3% and WL was present in 11.9%. In 9.1% WL information was missing. MNA classified 18.2% subjects malnourished and 42.0% at risk of malnutrition. Consideration of MNA and single markers amounted to 64.0% of residents at nutritional risk.

Comparison of MNA and single nutritional risk markers

Almost all (96.2%) residents classified malnourished by MNA also showed at least one single risk marker; 84.6% BMI ≤22 kg/m² and 73.1% LI. This correspondence was less pronounced in the group at risk of malnutrition (MNA 17-23.5 p.), with low BMI, LI or WL present in 51.7%. Eleven (9.6%) residents classified well-nourished by MNA yet showed a single marker of nutritional risk: nine a low BMI and two WL (tab.2).

Table 2: Prevalence of low BMI, weight loss and low intake in MNA categories

Single markers of nutritional risk	**Mini Nutritional Assessment**							
	malnutrition (<17 p.) (n=52)		risk of malnutrition (17-23.5 p) (n=120)		well-nourished (>23.5 p) (n=114)		total (n=286)	
	n	%	n	%	N	%	n	%
- low BMI [1]	44	84.6	41	34.1	9	7.9	94	32.9
- weight loss [2]	11	21.2	21	17.5	2	1.8	34	11.9
- low food intake	38	73.1	23	19.2	0	0.0	61	21.3
≥ 1 marker *	50	96.2	62	51.7	11	9.6	123	43.0
no marker *	2	3.8	58	48.3	103	90.4	103	57.0

[1] BMI ≤22 kg/m²,

[2] Weight loss >5% in last 3/ 10% in last 6 months

*either low BMI, weight loss or low intake

Functional status

In seven and 27 cases nursing staff could not judge cognitive status and depressive mood, respectively. Of those remaining, 59.0% showed moderate (36.9%) or severe (22.1%) cognitive impairment, 20.8% were rated moderately (16.2%) or severely (4.6%) depressed. One quarter of the participants (25.5%) was mobility-restricted, mostly moderate (20.6%) and to a lower extent severe (4.9%).

Functional status and nutritional risk

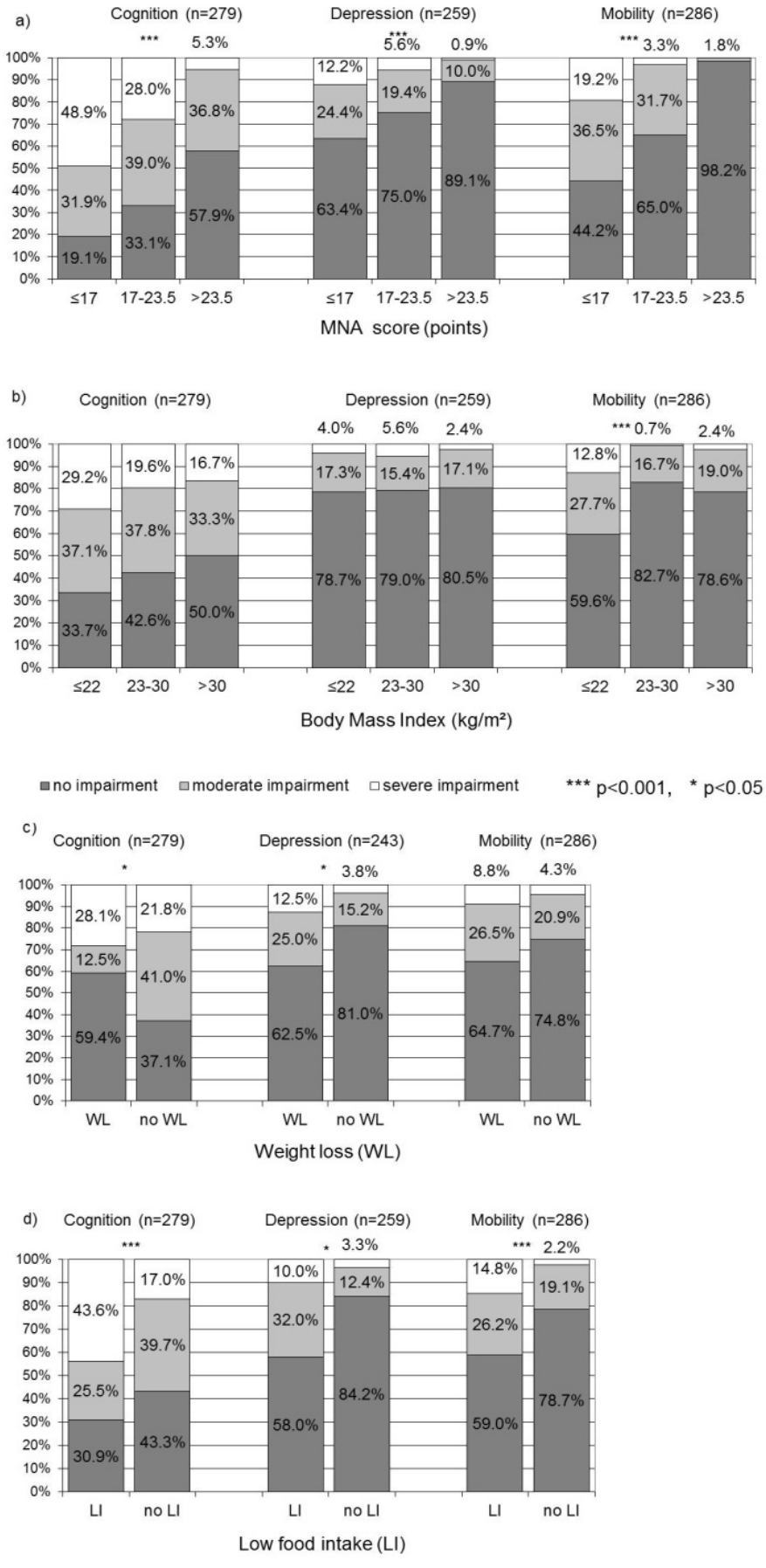

Figure 1: Prevalence of no, moderate and severe functional impairment in nursing home residents according to a) MNA, b) BMI, c) weight loss and d) low food intake

All nutritional risk markers were consistently associated with functional status (fig.1a-d). Prevalence of impaired function, in particular severe impairments, significantly increases with deteriorating MNA scores (fig.1a). The relationship between BMI and functional status is less pronounced but significant for mobility (fig.1b). WL was significantly associated with depressive mood and impaired cognition (fig.1c). LI was significantly related to all functional impairments (fig.1d).

Discussion

The present results highlight that malnutrition and its risk is still widely present and that these problems are yet unsolved in German nursing homes. The MNA identified nearly all residents showing important single markers of nutritional risk. Functional impairment was common and not only associated with low MNA scores but also with low BMI, WL and LI, that are risk factors negatively impacting health, cognition and life expectancy in the aged population.[4,5]

The alarming proportion of residents (64%) identified at nutritional risk during screening in this study indicates that the efforts undertaken in practice to reduce prevalence and unfavorable outcome, e.g. by implementing initiatives[21,22] or guidelines,[3,6,7,23] seems insufficient or without success. Uncertainty on the most practicable way to identify and treat elderly at risk persists, possibly intensified by the lack of a gold standard on the definition of malnutrition.[15]

In this study we applied the MNA as well as low BMI, WL and LI as additional, separate markers for nutritional risk to investigate whether MNA covers all residents with these important single risk markers possibly requiring special attention. Even though BMI as sole marker of nutritional risk can be misleading in persons with high BMI losing weight or in persons that always had low BMI values at younger age, it represents one of the few markers that are routinely documented in nursing homes and may be an indicator of undernutrition if low.[3,24]

MNA was assessed by interviewing nursing staff to limit interference with resident's cognitive or linguistic deficits[25] and obtain complete information, which is a strength of the study. However, nursing staff experienced the MNA as very time-consuming. This reflects one main barrier for regular use in practice[4] which could now be overcome with the recently developed 6-question short-form (MNA-SF) for improved practicability. Validation proved high sensitivity and specificity with the full version,[26] making it a useful alternative for screening in nursing homes.

Compared to MNA, that identified 60.2% being malnourished or at risk, prevalence of single nutritional risk markers was lower – 32.9% low BMI, 21.3% LI and 11.9% WL. This highlights

the wider approach of the MNA, also covering acute illness, psychological disorders and immobility, which contributes to its preventive nature and enables early nutritional measures.[19] Besides, it clearly shows that sole screening for single markers would certainly have neglected subjects with less obvious but also relevant risk factors for malnutrition in older people. A relevant percentage of nursing home residents are at risk of malnutrition as a consequence of functional disabilities, which may not be improved over time. This group may persistently stay at risk even after provision of nutritional support.

Therefore, in practice, further assessment of the root causes of the observed risk of malnutrition is important to find out if nutritional intervention is the appropriate sole measure to improve the situation, or if other measures including close monitoring of these residents are indicated to avoid further deterioration due to unresolved persisting causes, e.g. chewing or swallowing problems, that put them at risk of malnutrition.

An important finding is that all but 11 subjects (91.1%) with low BMI, WL or LI were identified by MNA, underscoring the broad identification of residents at nutritional risk achieved by the tool (tab.2). Those classified malnourished (<17 p.) virtually always (96.2%) showed one of the single nutritional risk markers as a clear sign of compromised nutritional status. In comparison, this proportion was lower (51.7%) in residents identified at risk of malnutrition (17-23.5 p.), indicating that a considerable share of this group is affected by an aggregation of other factors that contribute to their risk for malnutrition.

To date, it is still not quite clear which BMI cut-off is most appropriate for an elderly population and especially nursing home residents. Due to the fact that we aimed at identifying also subjects at risk of malnutrition we decided to choose a cut-off for BMI of 22 kg/m² which represents a value that corresponds to the 10th percentile of data recently assessed in a population of healthy non-Hispanic white elderly.[27] Furthermore, it was shown that a BMI of 22 already increased the risk of mortality and disability.[28]

Interestingly, 16 out of 42 residents with high BMI (>30 kg/m²) were also identified by MNA, confirming that BMI as sole marker for nutritional risk seems insufficient. For obese persons, provision of ONS may be questionable, but nevertheless they should receive attention regarding nutritional care, especially if concurrent WL and LI are observed. This was true for 2 and 3 cases in this population, respectively. Research is needed to define strategies on nutritional treatment of obese elderly showing indicators of nutritional risk, as they may require a different intervention than subjects with lower body weight.

As sole MNA use would have overlooked some cases classified well-nourished based on total score despite having low BMI (n=9) or WL (n=2) (tab.2), separately looking at each of these single markers would prevent missing subjects possible in need of nutritional support. Despite being part of the MNA (MNA-SF), BMI and WL are important single markers of

malnutrition and therefore also deserve separate consideration requiring low additional effort. This might be particularly important for subjects who lost weight, since WL is an important marker of malnutrition. Comparing the new MNA-SF to the three single markers (data not shown) resulted in 9 subjects being potentially overlooked instead of 11 with the full MNA. Considering also the previously mentioned high consistency with the long version, we would recommend the MNA-SF to improve screening practicability.

Participants of the present study were at high age, mostly female, with high care needs and thereby representative for nursing home populations, although the high rate of non-participation (46.4%) poses a risk of selection bias. Despite the benefits possibly resulting from screening for malnutrition, a high share of residents (or their proxies) was not willing to participate, leading to the observed high rate of refusals. For reasons of data protection it was also not possible to collect general characteristics for non-participating residents which would have enabled a comparison with participants to further evaluate the representativeness of the sample. During mealtimes, 49% of the participants were partly or completely dependent on nursing aid. Similar to previous findings,[29] need of both assistance during mealtimes and general care was significantly higher in subjects at nutritional risk compared to those without risk (tab.1). If appropriate support is lacking in daily routine, this enhances the risk of nutritional deficits and might partly explain the high prevalence of nutritional risk in our sample.

Oral nutritional support was at the time of the screening only allocated to residents identified at nutritional risk, but a considerable share (86.4%) did not receive ONS or snacks (tab.1). In agreement with studies where nutritional treatment was initiated in less than half of subjects at risk,[2,29,30] it underlines the lasting discrepancy between need for nutritional support, its recognition and implementation. Lack of time, knowledge and effort of physicians or nursing staff are regarded contributing factors[5,31] which should also be addressed in initiatives aiming at improved nutritional care.

The high prevalence rates of cognitive deficits (59%), depressive symptoms (20%) and immobility (25%) underline the relevance of these conditions in this setting. All three functional parameters were rated based on nursing staff perception, which is affected by subjectivity and thus, might be regarded inaccurate. Due to the screening nature of the study and the large number of residents included, it was unfortunately not possible to use standardized assessment tools for cognition, depression and mobility like Mini Mental State Examination (MMSE), Geriatric Depression Score (GDS) or gait speed, which might have been more accurate. However, it was the aim to get a rough classification, and besides this approach offered the advantage of a reduced number of missing values. By asking the responsible qualified nursing personnel who were closest to residents' everyday life and very familiar with their impairments and abilities, we feel confident that we obtained a reliable

estimate. Compared to data collection from medical records, this proceeding avoided the risk of missing diagnosis by physicians' underestimation that is particularly disadvantageous in the context of malnutrition where milder forms are also relevant.[32]

Similarly, low intake was assessed subjectively by asking the nursing staff, if food intake of the residents was involuntarily remarkable low during the last week. This definition was explained to the interviewed nursing staff responsible for the wards, who were therefore able to rate it in a standardized and comparable way. Again, the screening nature of the present study did not allow for a more precise and standardized assessment using plate diagrams or dietary records.

Our results clearly show that functional impairment was significantly more prevalent in residents with malnutrition or at risk (fig.1a-d). The observed relationship between nutritional risk markers and deteriorated function was especially pronounced for low MNA scores that were significantly associated with cognitive impairment, depressive mood and impaired mobility (fig.1a). This was in part expected since the MNA also includes functional aspects, but it also highlights the strength of the MNA to translate different functional impairments into an estimation of malnutrition risk. Other studies using the MNA in context with functional parameters showed an association between malnutrition according to MNA and depression,[33-35] and accelerated cognitive decline over a one-year follow-up in Alzheimer patients with initial low MNA score (<23.5 p).[36]

Remarkably, the association to functional impairment was also consistently found for every single nutritional risk marker (fig.1b-d). The relation of low BMI to functional impairment was less pronounced though and limited to a significant association to immobility. Likewise, in another nursing home sample BMI <21 kg/m² was strongly associated with sarcopenia,[37] underscoring the presumed role of good nutritional status in preventing its onset and consequent mobility loss.[38,39] With regard to mental impairment, BMI ≤22 kg/m² was only by tendency related to cognitive impairment in our study (fig.1b). This might be explained by the higher cut-off chosen for low BMI, as in a previous study with a lower cut-off <20 kg/m², BMI was significantly associated with reduced cognitive status.[40]

Low food intake is described as a multi-factorial problem[41] and in our study the only single marker that was significantly associated with all functional impairments (fig.1c). Both depression, dementia and physical impairment are regarded contributing factors to LI, and in accordance with our findings a previous study showed that low energy and nutrient intakes in an elderly community population were also related to frailty.[42] In daily routine, LI is the easiest marker to observe and close monitoring could enable early counteraction trying to avoid nutritional deterioration with its presumed negative impact on functionality. A closer look into the reasons of low food intake - for example inability to eat, reduced appetite or

general illness - and sub-classification of this marker represents an interesting aspect for future research which might provide additional valuable information for screening and preventing functional impairment among the nursing home residents.

The higher share of WL we observed in residents with cognitive impairment and depression (fig.1d) might in part be consequence of the before mentioned LI linked to these conditions. Similar to other risk markers, WL was particularly related to severe cognitive impairment and in line with other studies, it highlights the high nutritional risk of the cognitive impaired due to unintended WL,[43] affecting 30-40% demented elderly.[44]

In sum, the present results show a strong association between nutritional risk and functional impairment in nursing home residents contributing to a better understanding in this setting. It underlines that functionally impaired residents face an increased risk for malnutrition, indicated by different markers. They require early recognition and assistance by nursing staff, accompanied by interventions to improve nutritional status.[9,45,46] As a malnourished state is more difficult to correct in elderly than in younger subjects, the preventive approach gains additional importance[47] and is regarded a key benefit of the MNA, detecting early risk of malnutrition.[19] In practice, we would recommend to implement a routine screening at admission, followed by regular, perhaps quarterly repetition for a constant monitoring of the nutritional status of the residents that can easily change during the course of aging and may also be worsened by other than nutritional factors. Additionally, the weekly or at least monthly routine assessment of weight, intake and BMI would help to not only use this information as input for MNA-SF completion but also to recognize changes of nutritional status early.

For the interpretation of our results it has to be taken into account though, that these data provide no information on cause and consequence relationships between functionality and nutritional risk because of the study's cross-sectional nature. Our subsequent intervention study will investigate the benefit of oral nutritional support in nursing home residents at nutritional risk, clarify which subgroups profit most and whether functional impairment can be delayed or reversed by an improved nutritional status. For future research urgently needed in this setting,[9,13,20,46] it is important to include residents with both physical and mental impairment despite possible limitations regarding outcome assessment, as these are prominent conditions in this population.

Conclusion

The high prevalence of nutritional risk in nursing home residents in this study underscores the importance of regular screening for malnutrition which is not mandatory yet. The MNA enabled broad identification of nutritional risk, capturing almost all residents with low BMI,

weight loss or low intake. To avoid missing residents not covered by MNA (MNA-SF) who possibly benefit from nutritional intervention, we recommend also looking at BMI, weight loss and food intake separately which requires no additional effort, since these aspects are part of the MNA. The strong relationship between nutritional risk and functional impairment highlights the need to sensitize nursing personnel for nutritional problems, especially in functionally impaired residents, to initiate early intervention and thus, avoid further nutritional and functional deterioration.

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CHAPTER III

PUBLICATION NO.2

EFFECTS OF A LOW VOLUME, NUTRIENT- AND ENERGY-DENSE ORAL NUTRITIONAL SUPPLEMENT ON NUTRITIONAL AND FUNCTIONAL STATUS: A RANDOMIZED, CONTROLLED TRIAL IN NURSING HOME RESIDENTS

Stange et al., submitted to the Journal of American Medical Directors Association (JAMDA), February 2013

Abstract

Objectives: Although oral nutritional supplements (ONS) are known to be effective to treat malnutrition in the elderly, evidence from nursing home populations including the demented is rare, especially with regard to functionality and well-being. A known barrier for ONS use among elderly is the volume that needs to be consumed, resulting in low compliance and thus reduced effectiveness. This study aimed to investigate the effects of a low volume, energy- and nutrient-dense ONS on nutritional status, functionality and quality of life of nursing home residents.

Design: Randomized controlled intervention trial

Setting: Six nursing homes in Nuremberg and Fuerth, Germany

Participants: Nursing home residents affected by malnutrition or at risk of malnutrition

Intervention: Random assignment to intervention (IG) and control group (CG), receiving 2x125 ml ONS (600 kcal, 24 g protein)/d and routine care, respectively, for 12 weeks.

Measurements: Nutritional (weight, BMI, upper arm- and calf-circumferences, MNA-SF®) and functional parameters (handgrip strength, gait speed, depressive mood (GDS), cognition (MMSE), activities of daily living (Barthel ADL)) as well as quality of life (QoL, QUALIDEM) were assessed at baseline (T1) and after 12 weeks (T2). ONS intake was registered daily and compliance calculated.

Results: 77 residents (87±6y, 91% female) completed the study, 78% were demented (MMSE<17p) and 55% fully dependent (ADL≤30p). Median compliance was 73% (IQR 23.5-86.5%) with median intake of 438 (141-519) kcal/d. Body weight, BMI, arm- and calf-circumferences increased in the IG (n=42) and did not change in the CG (n=35). Changes of all nutritional parameters except MNA-SF significantly differed between groups in favor of the IG ($p<0.05$). GDS, handgrip strength and gait speed could not be assessed in 46, 38 and 49% of participants at T1 and/or T2, due to immobility and cognitive impairment. In residents able to perform the test at both times, functionality remained stable in IG and CG, except for ADLs, deteriorating in both groups. From 10 QoL categories, 'positive self-perception' increased in IG [78 (33-100) to 83 (56-100); $p<0.05$] and tended to decrease in CG [100 (78-100) to 89 (56-100); $p=0.06$], 'being busy' significantly dropped in CG [33 (0-50) to 0 (0-50); $p<0.05$].

Conclusion: Low-volume, nutrient- and energy dense ONS were well accepted among elderly nursing home residents with high functional impairment and resulted in significant improvements of nutritional status and, thus, were effective to support treatment of malnutrition. Assessment of function was hampered by dementia and immobility, limiting the

assessment of functionality, and highlighting the need for better tools for elderly with functional impairments. ONS may positively affect QoL but this requires further research.

Keywords: oral nutritional supplement; malnutrition; nursing home; intervention; compliance; nutritional status; functionality; quality of life

Introduction

Even though malnutrition is known to be highly prevalent among older people, and in particular in nursing home residents,[1] it remains an unsolved issue.[2,3] Worsening of nutritional status is a multifaceted problem with severe consequences, including loss of functionality and independence, adverse health implications,[4-8] and high malnutrition related costs for health care systems.[9] To counteract deterioration of nutritional status, it is important to recognize nutritional risk early and take appropriate measures.[10-12]

Oral nutritional supplements (ONS) are an effective and recommended option to treat or prevent malnutrition in older persons[13-15] but apparently the threshold to initiate nutritional intervention is high. Studies have shown positive effects of ONS on body weight and indicated functional improvement in older people resulting in clinical benefits with economic implications.[13-16] However, information on the effects of ONS in the nursing home population is limited in particular with regard to functionality and wellbeing.[13,17,18] Only five of the 15 nursing home or long term care trials included in the meta-analysis of Milne et al.[13] on protein and energy supplementation in older adults investigated functional outcomes. A small number of nursing home studies reporting both nutritional and functional parameters have recently been reviewed by Beck at al.[17] to analyze possible parallel effects of a nutritional intervention on both outcomes. They hypothesized that improved body weight through different kinds of nutritional support (e.g. ONS, fortified foods, milk powder) may translate into better functional outcomes and found such a concordance in three out of six studies showing beneficial effects on weight change. Both authors emphasize the need for more high-quality studies among nursing home residents to draw significant conclusions.[13,17]

Specifically, little is known about the effects of ONS in populations with high levels of cognitive and mobility impairment. Interestingly, dementia and immobility are often exclusion criteria in intervention studies with ONS[19-23] although these problems are widespread and well-known risk factors for malnutrition as recently confirmed.[24]

The volume that needs to be consumed can be a problem in ONS use among elderly due to appetite loss, which might result in low compliance, high product wastage and thereby reduced effectiveness.[25,26] A more concentrated, low-volume ONS has recently been developed to overcome this problem.[27-29]

The objective of this randomized controlled intervention trial was thus to investigate the effects of a low-volume, nutrient- and energy dense ONS on nutritional and functional status as well as quality of life of nursing home residents, deliberately including those with cognitive and mobility impairment.

Methods

Study design and study population

This randomized, controlled 12 week intervention trial was conducted between March 2009 and May 2010 in six nursing homes in Nuremberg and Fuerth, Germany. A standardized screening was performed to identify all residents with malnutrition or at risk of malnutrition who might possibly benefit from nutritional intervention. Exclusion criteria were an anticipated hospital stay (>1 week), renal disease (dialysis), end-stage disease and intolerance to ONS according to previous attempts to administer these. All subjects with either a Mini Nutritional Assessment (MNA®) score below 24 points, BMI ≤22 kg/m², a low food intake according to the nurses' perception or weight loss of ≥5% in the last 3 or ≥10% in 6 months, respectively, were invited to participate. Written informed consent was obtained from the residents or responsible proxies for both screening and participation in the intervention trial. Ethical approval was obtained from the Ethics Committee of the Universität Erlangen-Nürnberg.

Participants were randomly allocated to intervention (IG) or control group (CG). Randomization was performed in blocks of 6-10 subjects per ward, to balance differences between the wards, by closed envelopes.

Intervention

The IG was offered two bottles ONS with low volume (125 ml per bottle) and high nutrient- and energy-density (Fortimel Compact, Nutricia GmbH; 2.4 kcal/ ml, 12 g protein and 300 kcal per bottle) per day, supplementary to regular meals for 12 weeks. ONS were provided daily between meals to avoid a satiety effect on normal food intake. Care personnel were instructed to encourage residents to consume the amount offered, and to support compliance by varying flavors, providing smaller portion sizes more frequently or by adapting the time of offering. The CG received usual care, which included provision of home-made snacks or ONS when prescribed by the physician or provided by family members.

Compliance

ONS intake was registered daily by nursing staff as proportion (1/1, ¾, ½, ¼) consumed by the residents. Furthermore the study team visited the wards, daily during the first and last two weeks and at least 3 times per week during the rest of the study and collected and measured (ml) all leftovers. Compliance was calculated as percentage of the provided amount.

Nutritional intake

Food intake was recorded once, for three consecutive days, including one weekend day and two week days, 6-8 weeks after study start in participants of 5 of the 6 nursing homes. Trained research staff weighed and documented the amount of all foods offered and

leftovers after the residents' meals and in-between meals, including ONS consumed on these days. Energy- and nutrient intake was calculated using a nutrient analyzing software (EbisPro© Version 6.0) which is based on the German Food Code (BLS II, 3).

Baseline characteristics

Gender, age, duration of residency, level of care according to the German nursing insurance system (0= <45 (no), 1= 45-<120 (low), 2= 120-<240 (medium), 3= ≥240 (high) minutes need of basic care/day), mobility, medical conditions and number of prescribed drugs were collected from residents' files at baseline (T1). Residents were classified "mobile" when able to move at least 3m with or without walking aid (including wheelchair), "immobile sitting" when not being able to cover this distance or else "bedridden". Medical conditions included presence of pain and digestive problems, and medical diagnosis of dementia, depression, heart insufficiency, chronic kidney failure and diabetes mellitus.

Nutritional status

Body weight (BW) was measured in residents wearing normal clothing to the nearest 0.1 kg by using an electronic chair (Seco 950, Hamburg Germany) or a bath lift (Arjo, Finland) scale, depending on the residents' mobility status. Height was measured without shoes using a measuring rod to the nearest 0.1 cm. If patients were bedridden, height was calculated from resident's knee height measured to the nearest 0.1 cm using a knee height calliper.[30] BMI was calculated as weight (kg) divided by height squared (m^2). Upper arm- (UAC) and calf-circumferences (CC) were measured to the nearest 0.1 cm on the non-dominant side with a measuring tape. The recently revised and validated short version of the MNA (MNA-SF®)[31] was completed by interviewing the nursing staff. A score below 7 points indicates a state of malnutrition, 7-11 risk of malnutrition and >11 good nutritional status.

Mental function

Cognitive status was assessed by using the 30-question standardized Mini Mental State Examination (MMSE),[32] with a score of less than 24 indicating mild and below 18 severely impaired cognition. The 15-item geriatric depression scale (GDS) was applied to all residents cognitively capable to answer the questions, with a score of 6-10 indicating mild, and >10 points severe depressive symptoms.[33] Both MMSE and GDS questionnaires were directly addressed to residents during standardized interviews.

Physical function

Basic activities of daily living (ADL) according to Mahoney & Barthel[34] were assessed by interviewing the nursing staff. Values of 70-100 points were defined as independence, 35-65 as partial dependence and 0-30 as full dependence. Handgrip strength was measured in a

sitting position with a Vigorimeter (Martin, Tuttlingen, Germany) on the dominant side, to the nearest 0.2 kPA. From three consecutive measurements, maximum strength effort was used. Gait speed was measured over a 4 m distance in usual walking speed, using usual walking aid. Time was recorded to the nearest 1.0 second and gait speed calculated as m/s.

Quality of life

Quality of Life (QoL) was evaluated with QUALIDEM, a dementia-specific validated questionnaire[35,36] consisting of 37 items divided in 9 subscales covering relevant aspects determining an older persons quality of life: care relationship (7 items), positive affect (6 items), negative affect (3 items), restless tense behavior (3 items), positive self-perception (3 items), social relations (6 items), social isolation (3 items), feeling at home (4 items) and being busy (2 items). The items describe behaviors during the last week and are subjectively rated by the responsible nursing staff with 4 response options for each item: never, seldom, sometimes and often. A higher score indicates higher QoL in each of the subscales (100 max. for each) that are analyzed separately.

All nutritional and functional parameters and QoL were assessed at baseline (T1) and after 12 weeks (T2).

Data analysis and statistics

Statistical analysis was performed using SPSS© (version 20.0, SPSS Inc., Munich Germany). Following the intention-to-treat (ITT) approach, data of all residents originally assigned to either the IG or CG were analyzed unless residents died during the study.

For both intake and compliance, additional analysis was performed excluding all IG drop-outs discontinuing ONS consumption. For categorical variables, results are reported as absolute number and percentage, and to test differences between and within the groups, Chi²- and McNemar-Bowker-tests were used, respectively. Continuous variables, if normally distributed, are shown as means±SD, if not as median (interquartile range (Q1-Q3)). Differences between and within the groups were analyzed by unpaired and paired t-test for normally distributed data, and by the Mann-Whitney-U test and the Wilcoxon rank sum test, respectively, for non-parametric analysis.

Results were considered statistically significant at the $p<0.05$ level.

BW was the primary outcome parameter. A sample size calculation was performed (0.8 power to detect a significant difference $p<0.05$, two-sided) based on an estimated mean body weight of 55 kg and a mean difference in body weight between the groups at T2 of 1.5±2.2 kg comparable to results previously observed in this population.[37,38] To detect a significant difference between IG and CG, 35 subjects were needed for each group.

Results

Participants & baseline characteristics

From a total of 565 nursing home residents, 31 had to be excluded and 286 gave consent for screening. 182 subjects (64.0%) were identified at nutritional risk and suitable for the intervention trial.[24] Of these, 16 residents with BMI >30 m²/kg were excluded as ONS intervention was regarded as inappropriate. Written informed consent was obtained from 87 residents who were enrolled in the study and randomized into IG (n=42) and CG (n=35). Three participants of the IG (6.7%) and seven of the CG (16.7%) died during the study period (p=0.144). All 77 remaining subjects were reassessed after 12 weeks and included in the ITT analysis (fig.2).

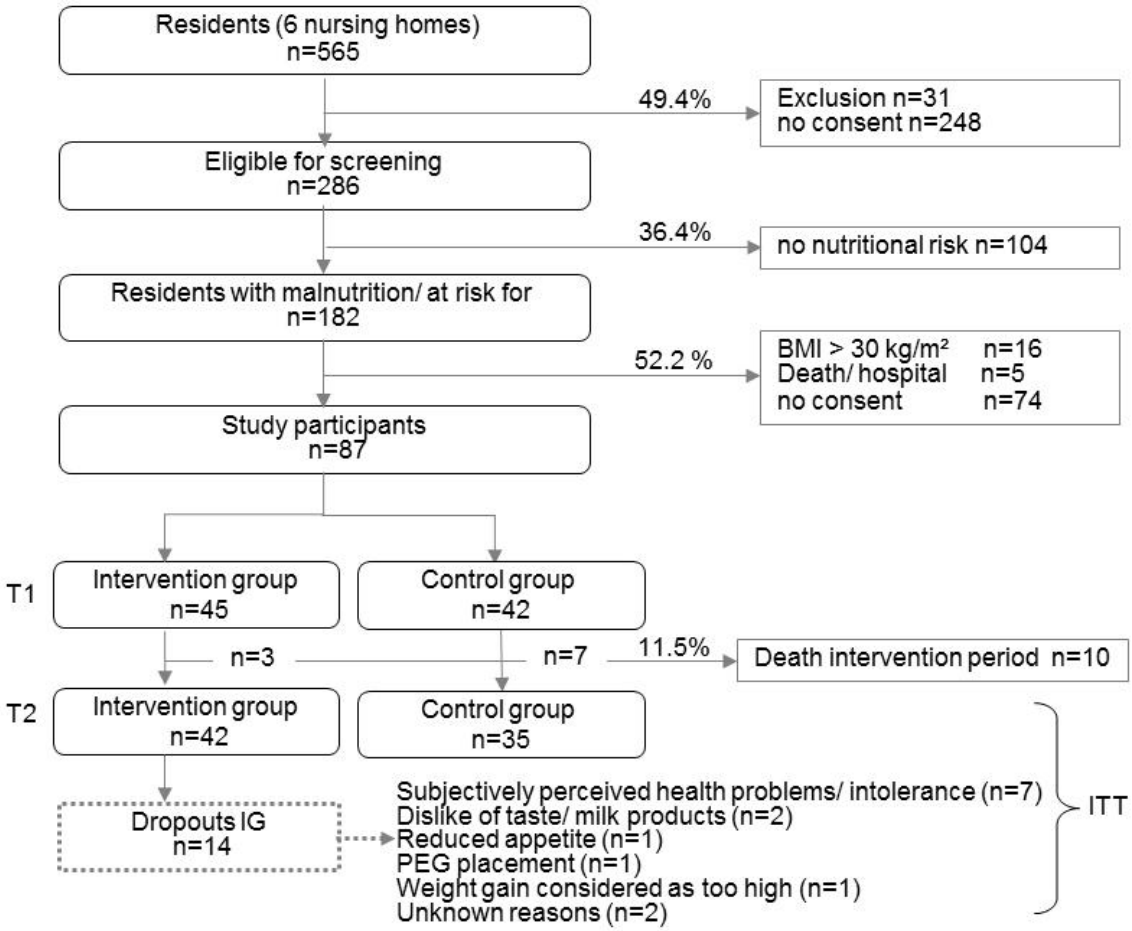


Figure 2: Flow chart of study participants

Residents were 87±6 years old, 90.9% were female. About one third were in need of highest level of care (36.4%) and immobile (sitting or bedridden) (35.1%), respectively. Residents

consumed 6±3 different drugs/day. Dementia was the most prominent medical condition (71.4%), followed by digestive problems (45.5%), cardiac insufficiency (37.7%) and pain (33.3%). Residents' characteristics were similar in the IG and CG at baseline except for differences in care level ($p<0.05$) (tab.3). For 7 subjects of the CG, and 5 of the IG, ONS had been prescribed prior to the study, which were continued in the CG and replaced by the study product in the IG.

Table 3: Baseline characteristics of study participants

		Intervention group (n=42)		Control group (n=35)		
		n/ mean	%/ ±SD	n/mean	%/ ±SD	*p*
General characteristics						
Gender	male	5	11.9%	2	5.7%	0.347
	female	37	88.1%	33	94.3%	
Age [years]		87	±6	86	±7	0.751
Length of stay [years]		4.1	±4.2	3.5	±3.3	0.543
Level of care	no	2	4.8%	5	14.3%	0.043
	I	6	14.3%	8	22.9%	
	II	21	50.0%	7	20.0%	
	III	13	31.0%	15	42.9%	
Mobility	mobile	27	64.3%	23	65.7%	0.929
	immobile sitting	12	28.6%	11	31.4%	
	bedridden	3	7.1%	1	2.9%	
Oral nutritional support	no support	29	69.0%	21	60.0%	0.591
	homemade highcaloric snacks	8	19.0%	7	20.0%	
	Oral nutrional supplements	5	11.9%	7	20.0%	
Medical condition						
Number of drugs		6	±3	5	±3	0.546
Dementia		32	76.2%	23	65.7%	0.311
Digestive problems		18	42.9%	17	48.6%	0.251
Cardiac insufficiency		17	40.5%	12	34.3%	0.577
Pain		15	35.7%	10	30.3%	0.244
Depression		13	31.0%	10	28.6%	0.820
Diabetes mellitus		12	28.6%	10	28.6%	1.000
Chronic kidney disease		13	31.0%	6	17.1%	0.162

p: Chi²-test, t-test

Compliance

Median ONS intake in the IG was 438 (Q1-Q3 141-519) kcal/d - equivalent to a median compliance of 72.9% (23.6-86.6%). 71.4% of the participants consumed at least half of the provided amount (≥300 kcal/ day). Fourteen residents (33.3%) discontinued ONS consumption, nine in the first 4 weeks. Excluding these 14 residents resulted in a median compliance of 81.9% (72.0-94.8%).

Nutritional intake

Food intake was recorded for 35 subjects of the IG and 31 of the CG. Baseline characteristics of these residents were not significantly different from those without dietary intake assessment (n=11). ONS consumption significantly increased total energy and protein intake per day in the IG (1263±372 to 1615±442 kcal and 41.3±15.1 to 54.9±18.2 g, both $p<0.001$), and resulted in a higher intake compared to CG for all micronutrients ($p<0.05$) except vitamin B12, vitamin A, magnesium and calcium. For energy and protein the difference in total intake between the groups did not reach statistical significance (IG 1615±442 vs. CG 1496±299 kcal, $p=0.211$, 54.9±18.2 vs. 48.0±12.1 g, $p=0.077$). Excluding participants who discontinued ONS consumption during the study period resulted in daily total intakes of 1781±337 kcal and 61.3±16.1 g protein in the IG, which were significantly higher than in the CG ($p<0.001$).

Nutritional status

Mean BW at baseline was 53.7±9.2 kg, mean BMI 22.8±3.3 kg/m² without differences between the groups. As shown in table 4, nutritional parameters significantly increased in the IG compared to the CG. BW increased by 1.2±2.4 kg in IG ($p=0.001$) and decreased by -0.5±2.3 kg in CG ($p=0.21$). The change of BW, BMI, UAC and CC significantly differed between IG and CG. There were no significant changes of MNA-SF.

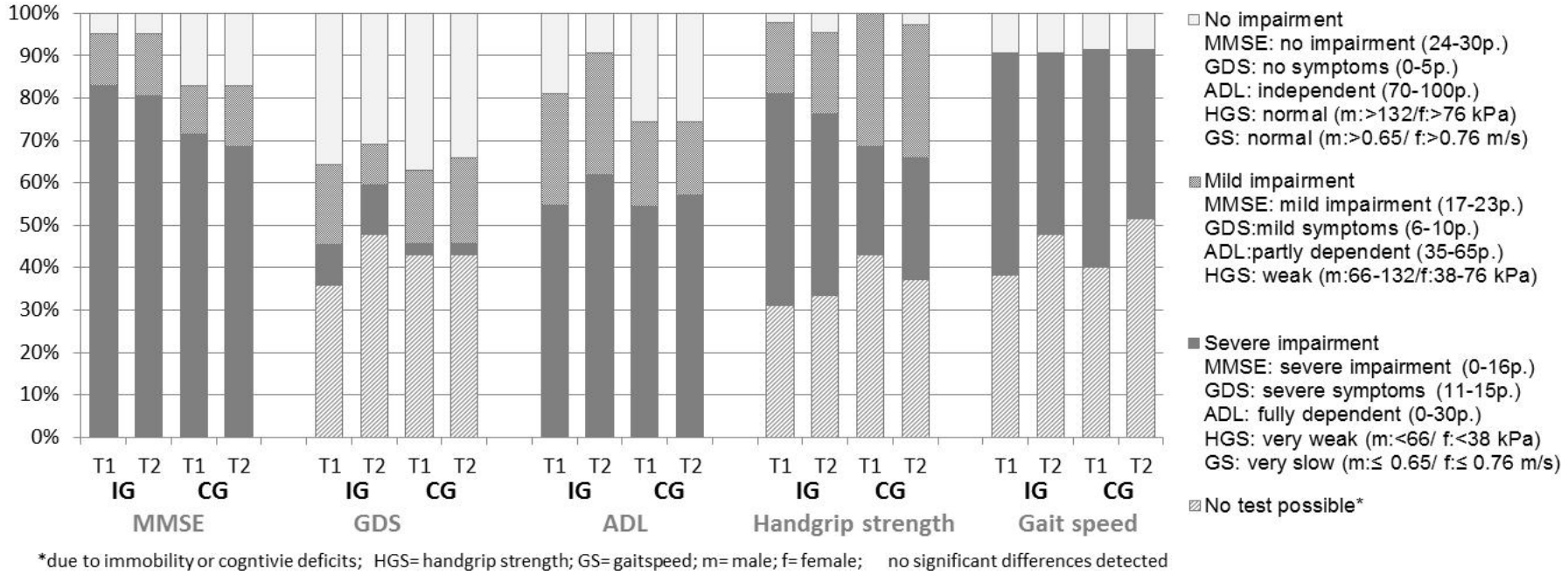
Table 4: Nutritional parameters in the intervention (IG; n=42) and control group (CG; n=35) at baseline (T1) and after 12 weeks (T2)

	IG			CG				
	T1	T2	*p* IG T1 vs.T2	T1	T2	*p* CG T1 vs.T2	*p*T1 IG vs.CG	*p* ΔIG-CG (T1-T2)
Weight [kg] §	54.6 ± 9.8	55.8 ± 9.7	0.001	52.7 ± 8.4	52.2 ± 8.4	0.210	0.372	0.002
BMI [kg/m²] §	23.0 ± 3.4	23.5 ± 3.3	0.002	22.5 ± 3.1	22.3 ± 3.1	0.206	0.484	0.002
UAC [cm] †	25.0 (22.5-27.2)	25.0 (22.4-27.0)	0.046	25.0 (23.0-27.5)	24.8 (22.8-27.0)	0.161	0.682	0.015
CC [cm] §	30.6 ± 4.3	31.0 ± 4.4	0.123	30.9±3.5	30.3 ± 3.3	0.084	0.762	0.018
MNA-SF [p.] †	9.0 (8.0-11.0)	10.0 (8.0-11.0)	0.597	9.0 (8.0-10.0)	9.0 (8.0-10.0)	0.319	0.357	0.800

Values as mean±SD/ med (Q1-Q3)

p IG/CG: § paired-t-test, † Wilcoxon rank sum test; differences within groups

p T1/ ΔIG-CG: § two sample-t-test, † Mann-Whitney-U-test; differences between the groups at baseline/ difference T1-T2



*due to immobility or cogntivie deficits; HGS= handgrip strength; GS= gaitspeed; m= male; f= female; no significant differences detected

Figure 3: Nutritional parameters in the intervention (IG; n=42) and the control group (CG; n=35) at baseline (T1) and after 12 weeks (T2)

Table 5: Functional parameters in the intervention group (IG) and the control group (CG) at baseline (T1) and after 12 weeks (T2)

	IG				CG					
	n	T1	T2	*p* IG T1 vs.T2	**N**	T1	T2	*p* CG T1 vs.T2	*p* T1 IG vs.CG	*p* ΔIG-CG (T1-T2)
MMSE [p.]	41	6 (1-14)	7 (0-14)	0.123	35	5 (0-18)	6 (0-20)	0.568	0.873	0.430
GDS [p.]	22	5 (4-9)	5 (2-10)	0.693	20	5 (2-6)	5 (3-8)	0.071	0.202	0.102
ADL [p.]	42	30 (10-50)	25 (5-40)	0.005	35	30 (10-65)	25 (5-65)	0.002	0.746	0.979
HGS [kPa]	28	32 (25-43)	34 (20-42)	0.746	20	40 (35-54)	43 (30-58)	0.203	0.069	0.407
GS [m/s]	22	0.41 (0.31-0.57)	0.47 (0.35-0.56)	0.259	17	0.44 (0.25-0.50)	0.33 (0.23-0.43)	0.653	0.589	0.590

HGS= handgrip strength; GS= gait speed ; values as med (Q1-Q3)

p IG/ CG: Wilcoxon rank sum test; differences within groups

p T1/ ΔIG-CG: Mann-Whitney-U-test; differences between the groups at baseline/ difference T1-T2

Table 6: Quality of life in intervention (IG) and control group (CG) at baseline (T1) and after 12 weeks (T2)) and after 12 weeks (T2)

	T1	**IG** (n=42) **T2**	*p* IG T1 vs. T2	**T1**	**CG** (n=35) **T2**	*p* CG T1 vs. T2	*p* T1 IG vs. CG	*p* ΔIG-CG (T1-T2)
Care relationship	86 (71-95)	83 (67-95)	0.433	90 (67-100)	86 (76-95)	0.940	0.486	0.569
Positive affect	81(50-100)	67 (56-89)	0.440	89 (56-100)	83 (67-94)	0.294	0.485	0.165
Negative affect	67 (44-89)	67 (33-89)	0.415	78 (56-89)	67 (56-89)	0.080	0.379	0.392
Restlessness	56 (33-78)	67 (33-89)	0.395	56 (33-78)	67 (33-89)	0.105	0.498	0.922
Positive self-perception	78 (33-100)	83 (56-100)	0.040	100 (78-100)	89 (56-100)	0.060	0.034	0.011
Social relationship	69 (50-83)	64 (50-83)	0.810	61 (50-83)	67 (44-83)	0.639	0.754	0.833
Social isolation	78 (56-100)	78 (56-89)	0.392	89 (67-100)	89 (67-100)	0.978	0.128	0.338
Feeling at home	92 (75-100)	83 (75-100)	0.695	100 (83-100)	100 (83-100)	0.450	0.015	0.778
Being busy	17 (0-50)	0 (0-50)	0.251	33 (0-50)	0 (0-50)	0.008	0.465	0.208

Values as med (Q1-Q3)

p IG/ CG: Wilcoxon rank sum test ; differences within the groups

*p*T1 / ΔT1-T2: Mann-Whitney-U-test; differences at baseline/ between the groups T1-T2

Mental & physical function

At baseline, 89.4% of residents suffered from mild (11.8%) or severe (77.6%) cognitive impairment and more than half (54.5%) were fully dependent in basic ADLs. Cognitive impairment and immobility impeded test performance of GDS in 46%, handgrip strength in 38% and gait speed in 49% of participants at T1 and/or T2. There were no significant differences between the groups at T1 (fig.3, tab.5). As shown in figure 3, percentages of functional impairment did not change significantly within the groups during the intervention and did not differ between the groups at T2. For residents able to perform the tests, functionality scores remained stable in IG and CG, except for ADL score that deteriorated in both groups ($p<0.05$) (tab.5).

Quality of life

The QUALIDEM-subscales 'positive self-perception' and 'feeling at home' differed between the groups at baseline, with higher scores in the CG. The score for 'being busy' was the lowest rated QoL-score at baseline in both groups. 'Positive self-perception' significantly increased in IG and tended to deteriorate in CG, resulting in a significant difference between the groups. The item 'being busy' deteriorated in CG only, while other items remained stable in both groups (tab.6).

Discussion

In this randomized controlled trial, a low volume, energy- and nutrient dense ONS significantly improved the nutritional status of nursing home residents with malnutrition or at risk of malnutrition and with a high level of mental and physical impairment compared to routine care. Residents receiving ONS also improved in one of the quality of life dimensions, whereas the CG deteriorated in one subscale. Functionality remained stable, except for ADL score that deteriorated in both groups.

Since it was the aim to intervene early before severe consequences of malnutrition appear, the present study also included subjects at risk of malnutrition, and used a broad definition of malnutrition or its risk. As typical for nursing home populations, participants had a high age, were mostly female, multimorbid and required a high level of care. A great proportion presented severe physical and mental functional impairments and high dependency at baselines (fig.3) which were not defined as exclusion criteria; therefore the population was older and more impaired compared to several other studies in this setting.[19,21,37]

The present study investigated the effects of ONS on both nutritional and functional status, as well as specifically the use of a new ONS formula, with a 37.5% lower than standard volume (125 ml vs. 200ml) and 60% higher energy density than usual formulas (2.4 vs. 1.5

kcal/ml). With few exceptions,[29,39,40] to date most ONS intervention studies used standard or high protein ONS in elderly.[16,26] Providing a low volume, energy dense variant addresses both the often reduced appetite and the barrier of consuming high volumes in older people.[41] This might improve the consumed amount of ONS prescribed and hence, compliance,[42-44] reduce product wastage,[45] optimize clinical benefits and save costs.

Compliance was closely monitored in this study and amounted to a median of 73%, resulting in a supplemental intake of 438 kcal/d. Exclusion of residents who discontinued ONS consumption increased compliance to 81%. This is markedly higher than in some previous studies in this setting (54-68%.[19,21,39,46]), and in a similar range as in other studies (86-91%[27,37,47]); in some studies, compliance has not been measured at all. Accuracy of these studies varies as different methods were used to record and analyze compliance, making the results difficult to compare.[26] Besides, it has to be taken into account that trial settings could also bias results, as compliance might differ in daily clinical practice compared to trial conditions. To further optimize compliance, it is important to acknowledge that other factors besides volume, e.g. nursing support, can also affect consumption. Although staff were encouraged to change mode and timing of distribution to maximize acceptance in the present study, it was for example not possible to convince all nursing personnel of the importance of the intervention. This may have lowered compliance, especially in those needing assistance for ONS consumption.

In line with the findings of others,[14,26] ONS intake improved total energy and protein intake with little suppressive effect on regular food intake. For practical reasons dietary records were not possible in all residents. As subjects with and without assessment did not differ in baseline characteristics, representativeness of the subgroup examined can be assumed. Increase of macronutrient intake of IG did not reach significance unless drop-outs were excluded. In contrast, micronutrient intake significantly increased, also without exclusion of drop-outs, which can be attributed to the high nutrient density of the study product. This is a relevant finding since it shows that ONS contribute to meeting nutrient requirements, which is often a problem for elderly suffering from appetite loss,[10] and neglected when alternatively energy-enriched meals are used that solely increase caloric intake.

The observed mean weight difference of 1.7 kg between the study groups after 12 weeks falls within the range of 1.5-2.2 kg after 8-24 weeks reported in comparable studies with ONS in nursing homes.[21,37,48] The difference results from a significant weight gain of 1.2 $\pm$2.5 kg in the IG and a CG weight loss of -0.5±2.3 kg, which resembles the reported CG weight loss in other studies.[21,37] The present CG also tended to decrease in all other nutritional parameters that increased in the IG, leading to a significant difference between the groups except for MNA (tab.4). This highlights the risk of routine care that not necessarily includes nutritional support for residents at nutritional risk. The absence of screening with subsequent

intervention and monitoring may lead to a slow but continuous worsening of nutritional status in subjects at risk, whereas ONS counteracts this development.

To address different domains of functionality – physical as well as mental function –various functional outcome parameters were applied. Both cognition and depressive mood have rarely been investigated in intervention trials with ONS in nursing homes so far[21,49] despite the close relation of both parameters with nutritional status.[24,50,51] While cognitive performance increased in a subgroup of participants with BMI <24.4 kg/m² in a comparable intervention study, GDS did not change.[21] In another trial with demented residents, MMSE decline was not reduced.[49] In our sample, both MMSE and GDS scores remained stable independent of the supplementation. Perhaps improvement of cognition and mood requires a combination of nutritional support and for example mental exercise programs or emotional support.[52]

Although benefits of ONS on physical functionality have been shown in geriatric patients,[23,53,54] only few studies using ONS in nursing homes investigated effects on muscle function and gait speed, [19,47] handgrip strength [48], or ADLs [21,37,49] until now.[18] Of these, two combined ONS with exercise training,[19,47] and only two trials also included severely demented subjects.[37,49] In line with the present results, studies did not report positive effects of ONS on ADLs[21,37,49] or handgrip strength.[48] One study found positive results for muscle power after a combined nutrition/ exercise intervention, however no improvement of gait speed,[19] which also did not change in our sample.

The results illustrate the difficulty to achieve improvements of functionality in nursing home residents despite the significant positive development of various nutritional parameters. Given the high level of functional impairment of the present vulnerable population at baseline, significant improvements may also not be realistically expected, so that stabilization and prevention of further deterioration could be regarded as successful intervention. Measurements like ADLs or MMSE may not be sensitive enough and unlikely to improve. The combination of a challenging high day-to-day intra-individual variability as well as pain, which was common among participants, can strongly interfere with strength/ performance measurements.[55] More suitable assessment tools for this target group that are sensitive for small changes and feasible for impaired residents might improve detection of small improvements, however, the clinical relevance of these might be questionable.

It also has to be taken into account that functional assessment was often hampered (fig.3); while handgrip strength and GDS were mainly hindered by cognitive impairment, gait speed was often not measurable due to immobility, both reducing the number of test participants. The absence of differences for these parameters may therefore in part be explained by a lack of power rather than a lack of physiological effect (type II error).

Finally, the lack of significance could also be derived from the conservative ITT approach chosen, as the analysis included all drop outs discontinuing the study ONS in the IG. This reduced overall compliance and might have overshadowed the analyzed ONS effects on outcomes. Moreover, seven CG residents continued ONS consumption routinely prescribed by their physicians. This most likely narrowed the difference in outcomes between groups through a certain amount of intervention in the control arm and highlights the difficulties of performing truly controlled trials in nutrition.

Although negative impact of malnutrition on well-being has been reported in elderly people[56] and a recent study reported on positive effects of ONS on QoL of care home residents[57], current knowledge about possible relations is still limited. It is not clear yet if an improved nutritional status also positively affects quality of life of aged, often multimorbid subjects, and in particular of cognitively impaired residents without ability to answer QoL related questions. Use of the QUALIDEM, a tool particularly designed and evaluated for demented,[35,36] helped to overcome this problem by interviewing the nursing staff being closest to the residents' daily life and capable of rating behavior and feelings. While 'positive self-perception' increased in supplemented residents, QoL tended to decrease in this dimension and deteriorated with respect to 'having something to do' among non-supplemented (tab.6). This positive development in favor of the IG supports recent data[57] and might indicate possible benefits of adequate nutritional support on QoL of residents which is one of the main goals strived for late in life.[58] Interpretation is difficult however, due to significant differences at baseline in one of the QoL dimensions under investigation, and requires further research.

There are several limitations to the study. It was neither placebo-controlled nor blinded, and dietary assessment was unfortunately impossible in some residents. For ethical reasons, the study was not truly controlled as subjects of the CG continued to receive nutritional support prescribed by physicians. The drop-out rate in the IG was relatively high and besides, functional impairment often reduced the number of patients being able to perform the tests and thus the power for analysis for these variables.

A strength of the present study is the wide assessment of outcome parameters which complies with the minimum dataset set as quality standard for nutrition intervention studies in the elderly[59] and enables good comparability with other studies. All assessments were highly standardized and performed by a small team of trained persons. Furthermore, all residents with cognitive or mobility impairment were included, which enabled to shed more light on this difficult population and to gain knowledge on the actual effectiveness of nutritional intervention in this group of elderly who are often at nutritional risk.[24,51,60,61] This also addresses the rarely discussed problem of limited clinical applicability of findings due to a lack of representativeness and generalizability which often results from exclusion of particularly demented subjects (70% in this study) in geriatric research.[62]

Conclusion

The present findings contribute to a better knowledge about the role of nutritional intervention in a population which is most vulnerable and at risk of malnutrition. The use of low volume, nutrient- and energy dense ONS in elderly nursing home residents resulted in significant improvements of nutritional status compared to control, and, thus, was effective to support treatment or prevention malnutrition in this population. The observed compliance indicates a good acceptance of low volume ONS among elderly nursing home residents with high functional impairment which may present a preferable alternative versus standard ONS. Assessment of function was hampered by dementia and immobility, limiting significance of the results for functionality. This highlights the need for a more differentiated approach to investigate the effects on functionality in future studies. Furthermore, it could be worth to either consider stabilization of functional status the maximum achievement of nutritional intervention or to put more focus on quality of life, a main goal late in life, as key outcome measure. ONS may positively affect QoL but further research is needed to better understand the effects of nutritional interventions on well-being of residents.

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CHAPTER IV

PUBLICATION NO.3

COMPLIANCE OF NURSING HOME RESIDENTS WITH A NUTRIENT- AND ENERGY-DENSE ORAL NUTRITIONAL SUPPLEMENT DETERMINES EFFECTS ON NUTRITIONAL STATUS

Stange et al., manuscript status for submission and publication in Clinical Nutrition

Abstract

Background & Aims: Oral nutritional supplements (ONS) are an effective strategy to avoid malnutrition, a persisting issue in nursing homes (NH). However, effectiveness of ONS can be limited by poor compliance, and little is known about compliance in the NH population. This study aimed to investigate compliance of NH residents with a low-volume, nutrient- and energy-dense ONS, analyse its role for the effects on nutritional status and identify residents' characteristics associated with compliance.

Methods: 77 NH residents (87±6y, 91%♀) with malnutrition or at risk of malnutrition were randomly allocated to an intervention group (IG) receiving 2x125 ml ONS (2.4 kcal/ml)/d for 12 weeks, or the control group (CG) with usual care. ONS intake was recorded daily and compliance calculated. Low and high compliance was defined as ≤30% and ≥80% of ONS consumed. Body weight (BW), BMI, upper-arm (UAC) and calf-circumference (CC) and MNA-SF were assessed at baseline and after 12 weeks. Associations between compliance and changes of nutritional parameters and residents' characteristics were analysed.

Results: Compliance (median (IQR)) was 73 (23.5-86.5)%. 71.4% consumed at least 300 kcal/d. Compliance was high in 35.7% and low in 28.6%. BW change was significantly higher in IG subjects with high compliance (+3.0 (+2.1;+3.8) kg, n=15) than those with low compliance (-0.2 (-2.2;+1.6) kg, n=12) and the CG (-0.1 (-1.2; +0.6) kg, n=35; $p<0.001$), and significantly correlated with compliance in IG ($r=0.691$; $p<0.001$). Significant differences and correlations were also identified for BMI, UAC and MNA-SF. High compliance was more prevalent in residents with malnutrition (66.7 vs. 27.3%) and chewing difficulties (77.8 vs. 24.2%). Low compliance was more prevalent in residents who were immobile (45.0 vs. 13.6%), depressed (33.3 vs. 6.7%) or had gastrointestinal complaints (GIC) (50.0 vs. 17.9%) (all $p<0.05$).

Conclusions: Compliance with the low volume, nutrient- and energy-dense ONS was high, indicating a good acceptance among residents. High compliance was related to significantly improved nutritional status compared to low compliance. Immobility, depression and GIC were identified as limiting factors while malnutrition and chewing difficulties were associated with higher compliance. To enhance the effectiveness of ONS these aspects need to be considered.

Keywords: Oral nutritional supplements, compliance, nursing home, intervention, malnutrition

Introduction

Oral nutritional supplements (ONS) are regarded an effective strategy to avoid and treat malnutrition in elderly,[1,2] which is still a very prevalent issue in nursing homes.[3-7] To avoid the various detrimental consequences of malnutrition[8-10] it is important to intervene early to counteract deterioration of nutritional status.[6,11-13]

For the success of a nutrition intervention with ONS, compliance is one key element that deserves special attention but is only included as side aspect in most existing trials. Results from nursing home studies reporting compliance with ONS are diverse, ranging from 54-91%[14-20] observed compliance, and without further data on possible effects of compliance on outcome or influencing factors contributing to these rates.

Interestingly, a recent systematic review investigating compliance with ONS across different settings found that overall compliance is particularly good with higher energy-density ONS.[21] Similarly, it has been suggested that compliance of elderly persons might be improved with higher energy density and concurrent low volumes.[22] Especially in older people, often suffering from reduced appetite and limited intakes, difficulties may arise when larger volumes need to be consumed.[23] To overcome this possible barrier for ONS consumption, recently a novel, low-volume, nutrient- and energy-dense formula was developed and first findings indicate an improved compliance in malnourished subjects.[16,24,25] By facilitating ONS consumption, improving compliance, and concurrently reducing wastage, both therapeutic and economic effectiveness of ONS prescriptions might be optimized.[26-29]

Even though an impact of compliance on the effectiveness of nutritional interventions could be anticipated, there is to date no information from nursing home studies on the specific effect of different compliance levels on residents' outcome and particularly nutritional parameters.

It is important to recognize that compliance in elderly can be influenced by various factors.[22,23,30] It has been reported that factors related to the environment, the food and the person, can affect nutritional intake in general in elderly subjects.[22] With respect to ONS intake, mode and timing of ONS offering, and the attitude of nursing staff are relevant environmental factors that can impact consumption. Adequate assistance during nutritional interventions becomes even more important the higher the residents' degree of dependency[31,32] In addition, both taste and flavour of ONS may impact consumption behaviour and possibly compliance [23,33,34] and recently, age and critical illness were identified as person-related factors that were negatively associated with compliance.[21] It seems logical, that also other individual characteristics of elderly subjects in need of nutritional support, like presence of functional impairment or specific nutritional problems might play a major role,

however comprehensive research on compliance and its influencing factors in the nursing home population is missing.

To obtain better knowledge on compliance with ONS in the nursing home setting, objectives of the present paper were to 1. investigate the compliance of nursing home residents with a low-volume, nutrient- and energy dense ONS, 2. analyse the role of compliance for the effectiveness of the intervention with ONS and 3. identify resident characteristics associated with compliance.

Materials & Methods

Study design and study population

This report is part of a randomized, controlled 12 week intervention trial investigating the effects of a nutrient- and energy dense ONS on nutritional status, functionality and quality of life, which was conducted between March 2009 and Mai 2010 in six nursing homes in Nuremberg-Fürth, Germany.[35] To identify residents at nutritional risk who would possibly benefit from nutritional intervention, a standardized screening was performed. All residents, with a Mini Nutritional Assessment (MNA®) score below 24 points, BMI ≤22 kg/m², low recent food intake or weight loss ≥ 5% or 10% in the last 3 or 6 months, respectively, were regarded as at nutritional risk and invited to participate. Informed consent for participation was asked from the residents or responsible proxies. Ethical approval was obtained from the ethical committee of the Friedrich-Alexander Universität Erlangen-Nürnberg.

Residents' characteristics at baseline

Information on gender, age, duration of residency, level of care according to the German nursing insurance system (0 = <45 min, 1 = 45-120 min, 2 = 120-240 min, 3 = ≥240 min need of basic care per day), comorbidities, number of prescribed drugs per day and current use of nutritional support were collected at baseline from residents' files. Mobility was recorded as mobile (able to move at least 3 m with or without walking aid including wheelchair), immobile sitting or bedridden.

Mini mental state examination (MMSE)[36] and geriatric depression scale (GDS)[37] were assessed in personal interviews with the residents to evaluate level of cognitive impairment and depressive mood, respectively. A MMSE score less than 24 indicated mild and a score below 18 severe cognitive impairment, a GDS score of 6-10 was defined as mild and >10 points severe depressive symptoms. Ability to perform basic activities of daily living (ADL) were assessed according to Barthel & Mahoney[38] by interviewing the nursing staff. Values of

70-100 points were defined as independent, 35-65 as partially dependent and 0-30 as fully dependent.

Presence of anorexia, eating dependency, swallowing difficulties, chewing difficulties and gastrointestinal complaints (GIC) was also assessed during interviews with the responsible nursing staff.

Intervention

To allocate all participants randomly to intervention (IG) or control group (CG), randomization was performed in blocks of 6-10 by wards to balance differences between the wards, using blinded envelopes. The IG received in addition to their normal meals two oral nutritional supplements (ONS) with a low volume and high nutrient- and energy-density (Fortimel Compact, Nutricia GmbH; 125 ml, 24 g protein and 300 kcal/ bottle, 2.4 kcal/ ml) daily for 12 weeks. Residents assigned to the CG received usual care, which could include the use of ONS when prescribed by the physician or provided by family members.

Compliance

ONS intake was registered daily by nursing staff who estimated the proportion (¼, ½, ¾,1/1) of each ONS bottle consumed by the residents. This documentation was regularly controlled by the study team, which additionally measured leftovers (ml) and counted empty bottles during visits of the wards, daily during the first and last two weeks and at least 3 times per week during the rest of the study period. Compliance was calculated as the percentage actually consumed of the provided amount of ONS per day, based on the mean of both compliance documentations. Low, medium and high compliance was defined as ≤30%, >30-<80% and ≥80%, respectively, in order to achieve subgroups of comparable size.

Nutritional status

Nutritional status was assessed at baseline (T1) and after 12 weeks (T2). Body weight (BW) was measured in residents wearing normal clothing to the nearest 0.1 kg by using an electronic chair (Seco 950, Hamburg Germany) or a bath lift (Arjo, Finland) scale, depending on the residents' mobility status. Standing height was measured without shoes using a measuring rod to the nearest 0.1 cm. If patients were bedridden, height was calculated from resident's knee height measured to the nearest 0.1 cm using a knee height calliper.[39] BMI was calculated as weight (kg) divided by height squared (m^2). Upper arm- (UAC) and calf-circumferences (CC) were measured to the nearest 0.1 cm on the non-dominant side with a measuring tape. The recently revised and validated short form of the MNA (MNA-SF®)[40] was completed by interviewing the nursing staff. A score below 7 points indicates malnutrition, 7-11 risk of malnutrition and >11 normal nutritional status.

Data analysis and statistics

Statistical analysis was performed using SPSS© (version 20.0, SPSS Inc., Munich Germany). All residents originally assigned to either the IG or CG were analysed according to the intention-to-treat (ITT) approach, residents who died during the study were excluded. Results are reported as absolute numbers and percentages, mean values and standard deviation or median and interquartile range (Q1-Q3). Changes of nutritional parameters in different compliance groups (low/ medium/ high) and the CG were compared by ANOVA for parametric parameters or the Kruskall-Wallis test for non-parametric parameters. Correlation between change of nutritional parameters and compliance was analysed by Spearman's coefficient in the IG.

Associations of high and low compliance with residents' characteristics were analysed by Chi^2-test comparing the groups with a compliance ≤30 vs. >30% and <80 vs. ≥80%, respectively. Residents' characteristics were classified as follows: mobile vs. immobile (immobile sitting/ bedridden), low (0-2) vs. high (3) level of care, daily medication > vs. < 4 drugs/day, severe (MMSE<17 p.) vs. mild/ no cognitive impairment (≥17 p.), severe/ mild (GDS>5 p.) vs. no depressive symptoms (≤5 p.), full dependency (ADL score ≤ 30) vs. partial dependency/ independency (>30 p.), no vs. mild/severe forms of anorexia, malnutrition (MNA-SF ≤7 p.) vs. at risk for malnutrition/ normal nutritional status (>7 p.), eating independently/ with difficulties vs. need for assistance, presence of swallowing difficulties, chewing difficulties or gastrointestinal complaints vs. absence of these problems, respectively.

Results were considered statistically significant at the $p < 0.05$ level. In view of the exploratory nature of analyses no alpha adjustment techniques were employed.

BW was the primary outcome parameter. A sample size calculation was performed (0.8 power to detect a significant difference p<0.05, two-sided) based on an estimated mean body weight of 55 kg and a mean difference in body weight between the groups at T2 of 1.5±2.2 kg comparable to results previously observed in this population.[20,41] To detect a significant difference between IG and CG, 35 subjects were needed for each group.

Results

Participation

From a total of 565 nursing home residents, 31 had to be excluded due to an age below 65 years (n=4), short-term care (n=4), terminal condition (n=1), hospital stay (n=2), tube-feeding (n=18) or dialysis (n=2) and 286 gave consent for screening. Of these, 182 subjects (64.0%) were identified at nutritional risk and suitable for the intervention trial (fig.4).[3] Of these, 16 residents with BMI >30 kg/m² were excluded as ONS intervention was regarded as inappropriate.

Written informed consent was obtained from 87 residents who were enrolled in the study and randomized into IG (n=45) and CG (n=42). Three participants of the IG (6.7%) and seven of the CG (16.7%) died during the study period (p=0.144). All 77 remaining subjects were reassessed after 12 weeks.

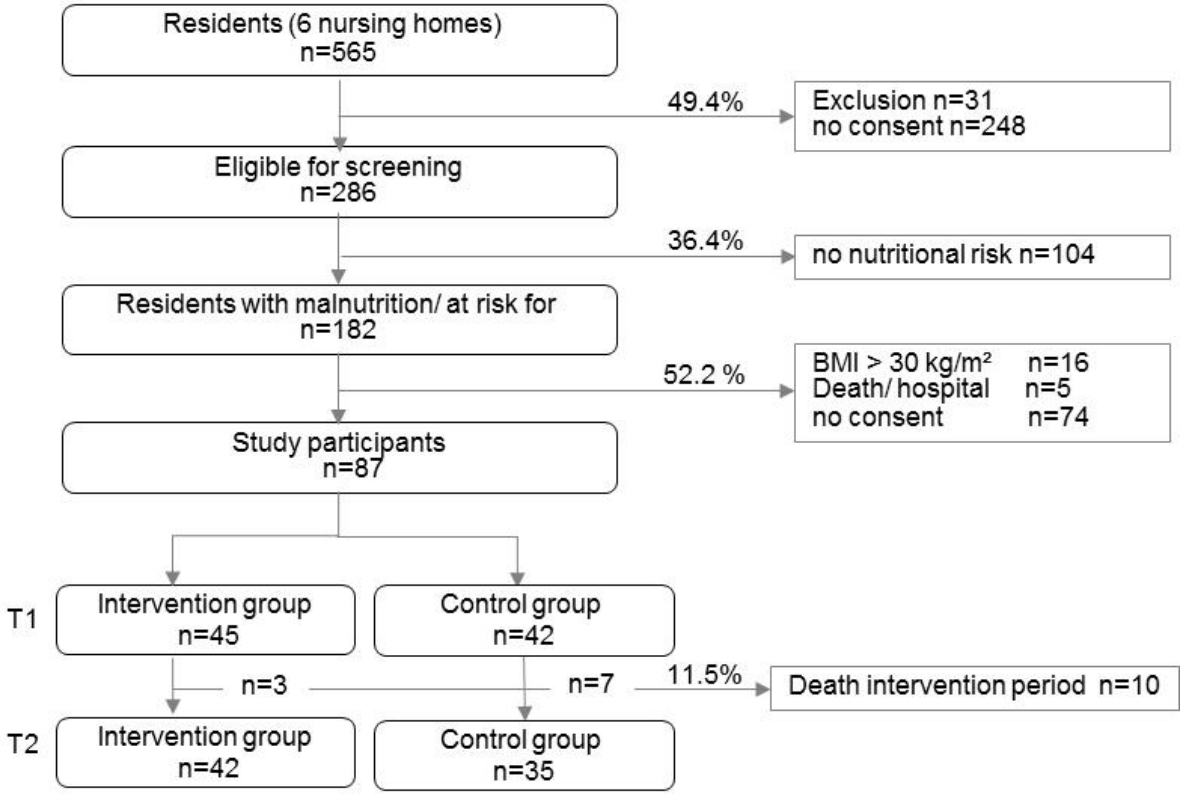

Figure 4: Flow chart of study participants

Residents' characteristics at baseline

Residents were 87±6 years old, 90.9% were female. Mean duration of residency was 3.8±3.8 years. About one third were in need of highest level of care (36.4%) and residents consumed 6±3 different drugs/ day. For 7 subjects of the CG, and 5 of the IG, ONS had been prescribed prior to the study, which were continued in the CG and replaced by the study product in the

IG). Half of the participants was impaired in mobility, either being immobile sitting (40.3%) or bedridden (9.1%), and 83.1% were partly (23.4%) or fully (59.7%) dependent in basic ADLs. 89.4% suffered from severe (77.6%) or mild (11.8%) cognitive impairment, depression was present in 24.7%. Residents' characteristics were similar in the IG and CG at baseline except for differences in care level ($p<0.05$). All residents' characteristics, including medical condition are represented in table 7 for IG and CG.

Table 7: Residents' characteristics at baseline in intervention (IG) and control group (CG)

		IG (n=42)	CG (n=35)	*p*
		%/ mean±SD	%/ mean±SD	
General characteristics				
Gender	male	11.9	5.7	n.s.
	female	88.1	94.3	
Age (years)		87±6	87±7	n.s.
Duration of residency (years)	< 1	23.8	20.0	n.s.
	1-3	31.0	37.1	
	3-5	16.7	20.0	
	> 5	28.6	22.9	
Level of care	no	4.8	14.3	<0.05
	I	14.3	22.9	
	II	50.0	20.0	
	III	31.0	42.9	
Oral nutritional support	no support	69.0	60.0	n.s.
	high caloric snacks	19.0	20.0	
	oral nutritional supplements	11.9	20.0	
Medical condition				
Daily number of drugs		6±3	5±3	n.s.
Dementia		76.2	65.7	n.s.
Digestive problems		42.9	48.6	n.s.
Cardiac insufficiency		40.5	34.3	n.s.
Pain		35.7	30.3	n.s.
Depression		31.0	28.6	n.s.
Chronic kidney disease		31.0	17.1	n.s.
Diabetes mellitus		28.6	28.6	n.s.
Chewing difficulties		21.4	11.4	n.s.
Swallowing difficulties		9.5	11.4	n.s.
Functionality				
Mobiltiy	mobile	52.4	48.6	n.s.
	immobile sitting	35.7	45.7	
	bedridden	11.9	5.7	
Cognition (MMSE)	no impairment (24-30p.)	4.9	17.1	n.s.
	mild impairment (17-23p.)	12.2	11.4	
	severe impairment (0-16p.)	82.9	71.4	
Depression (GDS)	no symptoms (0-5p.)	35.7	37.1	n.s.
	mild symptoms (6-10p.)	19.0	17.1	
	severe symptoms (11-15p.)	9.5	2.9	
	test not available §	35.7	42.9	
ADL	independent (70-100 p.)	9.5	25.7	n.s.
	partly dependent (35-65 p.)	28.6	17.1	
	fully dependent (0-30 p.)	61.9	57.1	

MMSE = Mini Mental State Examination; GDS = Geriatric Depression Scale; ADL = Activities of Daily Living
§ test performance not possible due to cognitive impairment; *p:* Chi²-test, t-test

Nutritional status at baseline

According to MNA-SF 22.1% were malnourished, 66.2% at risk of malnutrition. Mean BMI was 22.8±3.3 kg/m². Nutritional parameters at baseline in IG and CG are presented in tab. 8.

Table 8: Nutritional status at baseline in intervention (IG) and control group (CG)

		IG (n=42)	CG (n=35)	*p*
		%/ mean±SD	%/ mean±SD	
MNA-SF score [pts]	≥ 12 (well-nourished)	9.5	14.3	n.s.
	8-11 (risk of malnutrition)	69.0	62.9	
	0-7 (malnourished)	21.4	22.9	
Body weight [kg]		54.5 ± 9.9	52.7 ±8.4	n.s.
BMI [kg/m²]		23.0 ±3.4	22.5 ±3.1	
BMI [kg/m²] classes	<= 22 kg/m²	47.6	60.0	n.s.
	23 - 30 kg/m²	52.4	40.0	
Weight loss (≥5/10% in past 3/6 months)		11.9	17.1	n.s.
Low food intake		26.2	45.7	n.s.
Upper arm circumference [cm]		24.9 ±3.4	25.6 ±3.9	n.s.
Calf circumference [cm]		30.6 ±4.3	30.9 ±3.5	n.s.

MNA-SF = Mini Nutritional Assessment Short-form; BMI = Body Mass Index
p: Chi²-test, t-test

Compliance

Median ONS intake in the study group was 438 (Q1-Q3 141-519) kcal/d – equivalent to a median compliance of 72.9 (23.6-86.6) %. 71.4% of the participants consumed at least half of the provided amount (≥300 kcal/ day). Compliance was high in 35.7% (n=15) and low in 28.6% (n=12) (fig.5).

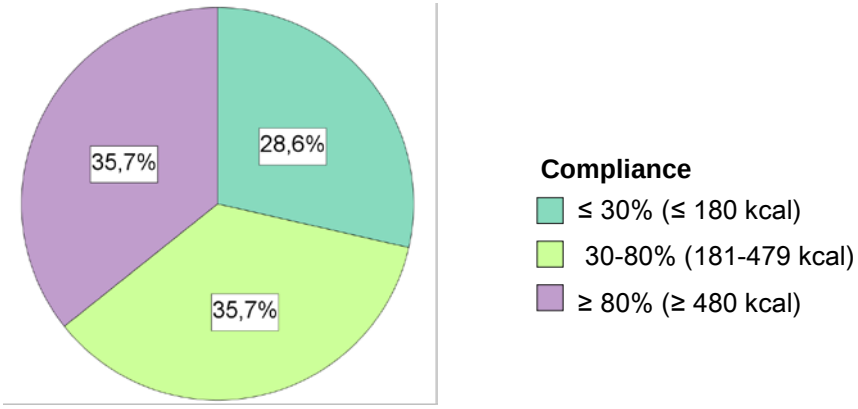

Figure 5: Compliance of nursing home residents (n=42) during a 12 week ONS intervention

The group with low compliance completely consisted of residents who discontinued ONS consumption, showing a median compliance of 14.3 (4.3-23.6) %. In total, fourteen residents discontinued ONS consumption, nine of these in the first 4 weeks. Reasons were subjectively perceived health problems/ intolerance (n=7), dislike of taste/ milk products (n=2), unknown (n=2), reduced appetite (n=1), PEG placement (n=1), and weight gain considered as too high (n=1). In only two cases the nursing personnel reported an association between the reasons for discontinuation and the ONS.

Compliance and nutritional status

For all nutritional parameters except for CC, significant differences between the compliance groups and also the CG was observed ($p<0.001$). Subjects with high compliance showed higher positive changes than subjects with lower compliance and the control subjects (tab.9). In subjects with high compliance, a median weight gain of 3.0 kg was observed, whereas more than half of the subjects with low compliance and of the CG lost weight ($p<0.001$) (fig.6).

Table 9: Change of nutritional parameters (T1-T2) in the control (CG) and intervention group (IG) and correlation between compliance and change of nutritional parameters in the IG

Δ T1-T2	**CG** (n=35)	**IG** – Compliance **≤ 30%** (n=12)	**>30 - <80%** (n=15)	**≥ 80%** (n=15)	*p**	**correlation** r $	*p*
BW [kg] §	-0.10 (-1.20; 0.60)	-0.15 (-2.15; 1.50)	0.90 (-1.40; 2.50)	3.00 (2.10; 3.80)	0.000	0.691	0.000
BMI [kg/m²]§	-0.05 (-0.47; 0.24)	-0.06 (-0.90; 0.71)	0.38 (-0.56; 1.01)	1.16 (0.84; 1.56)	0.000	0.620	0.000
UAC [cm] *	-0.50 (-0.90; 0.40)	-0.45 (-0.60; 0.50)	0.00 (-0.70; 0.80)	1.10 (0.40; 1.50)	0.001	0.487	0.001
CC [cm] §	-0.40 (-1.20; 0.50)	0.10 (-0.40; 0.75)	0.80 (-1.20; 1.80)	0.60 (0.20; 1.20)	0.128	0.043	0.787
MNA-SF [p]*	0.00 (-1.00; 2.00)	-2.00 (-3.00; 0.00)	0.00 (-2.00; 2.00)	2.00 (1.00; 3.00)	0.007	0.600	0.000

p:* § ANOVA, * Kruskall-Wallis-test ; *p:* r$ Spearman's correlation coefficient
T1 = Baseling, T2 = after 12 weeks, BW = body weight, BMI = Body Mass Index, UAC = upper arm circumference, CC = calf circumference, MNA-SF = Mini Nutritional Assessment Short-form

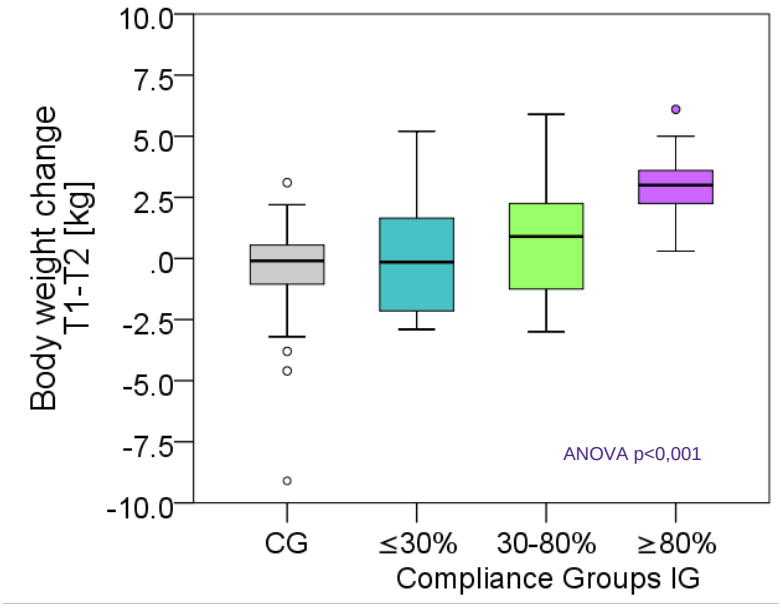

Figure 6: Boxplots of body weight change after 12 weeks in the control group (CG, n=35) and in different compliance groups of the intervention group (IG; ≤ 30%: n=12, 30-80%: n=15, ≥80%: n=15)

There were significant correlations between change of body weight, BMI, UAC and MNA-SF and compliance in the IG (all p<0.01) (tab.9). The correlation between body weight change and compliance is illustrated in figure 7.

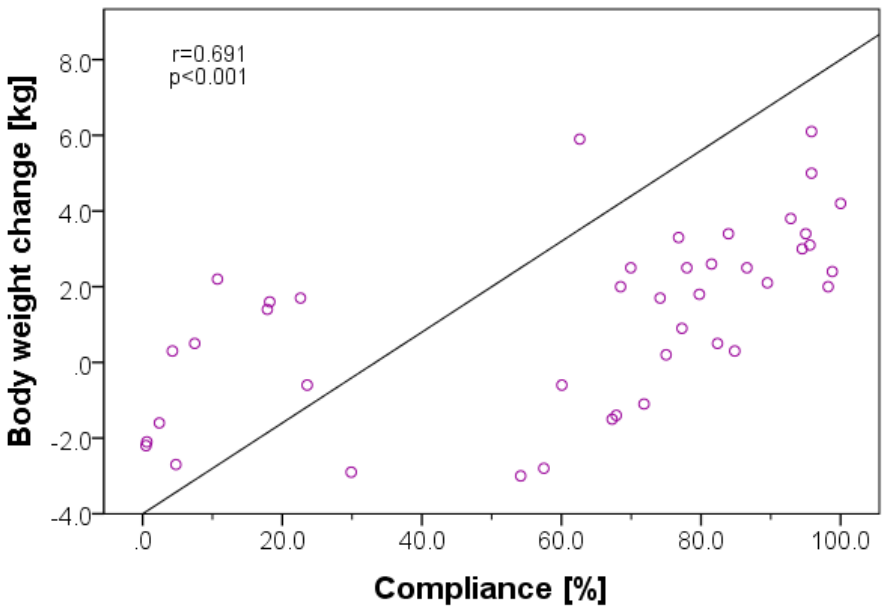

Figure 7: Scatter plot of mean compliance and body weight change after 12 weeks (n=42)

Compliance and residents' characteristics

High compliance was significantly more prevalent in malnourished subjects compared to those at risk and well-nourished, in residents with chewing disorders vs. no disorders and residents without vs. those with gastrointestinal complaints. Low compliance was more frequent in immobile vs. mobile, in residents with a number of daily drugs < 4 vs. ≥ 4, in depressed vs. not depressed, and when gastrointestinal complaints (GIC) were present vs. no complaints (tab.10).

Table 10: Prevalence of low (≤30%), medium (>30-<80%) and high (≥80%) compliance according to resident characteristics

Resident characteristics	Total (n=42)	Compliance ≤ 30% (n=12)	<30->80% (n=15)	≥ 80% (n=15)		
	n	%	%	%	p1	p2
Mobility						
mobile	22	13.6	50.0	36.4	0.025	0.927
immobile	20	45.0	20.0	35.0	*	
Level of care						
low-medium	29	27.6	37.9	34.5	0.833	0.804
high	13	30.8	30.8	38.5		
Number of daily drugs						
< 4 drugs/ day	8	62.5	12.5	25.0	0.018	0.482
≥ 4 drugs/ day	34	20.6	41.2	38.2	*	
Dementia						
no/ mild (MMSE≥17p.)	7	14.3	57.1	28.6	0.339	0.733
severe (MMSE<17p.)	34	32.4	32.4	35.3		
Depression						
no symptoms (GDS≤5p.)	15	6.7	53.3	40.0	0.048	0.657
depression (GDS>5p.)	12	33.3	25.0	41.7	*	
Activities of daily living						
independent/ need of assistance (ADL>30p.)	16	18.8	50.0	31.2	0.269	0.636
fully dependent (ADL≤30p.)	26	34.6	26.9	38.5		
Anorexia						
no anorexia	30	26.7	36.7	36.6	0.666	0.839
mild/ severe anorexia	12	33.3	33.3	33.4		
MNA-SF						
well-nourished/ risk of malnutrition (> 7 p.)	33	33.3	39.4	27.3	0.191	0.029
malnourished (≤7 p.)	9	11.1	22.2	66.7		*
Eating dependency						
independent/ difficulties	29	31.0	37.9	31.0	0.598	0.344
need for assistance	13	23.1	30.8	46.2		
Chewing difficulties						
no	33	33.3	42.4	24.2	0.191	0.003
yes	9	11.1	11.1	77.8		*
Swallowing difficulties						
no	38	28.9	34.2	36.8	0.868	0.638
yes	4	25.0	50.0	25.0		
Gastrointestinal complaints						
no	28	17.9	35.7	46.4	0.030	0.040
yes	14	50.0	35.7	14.3	*	*

Chi²-test; p1 ≤ 30 vs. >30% ; p2 <80 vs. ≥ 80%; MMSE= Mini Mental State Examination, GDS=Geriatric Depression Score; MNA- SF = Mini Nutritional Assessment-Short Form

Discussion

In this randomized, controlled trial, compliance with a low volume, nutrient- and energy dense ONS in nursing home residents with malnutrition or at risk of malnutrition amounted to a median of 73%, indicating a good acceptance. High compliance (≥80%) was associated with significant greater changes of various nutritional parameters, including body weight and MNA-SF score, than in the CG or in residents with low compliance (≤30%). A low compliance was significantly associated with presence of immobility, less than 4 drugs/d, depression and gastrointestinal complaints (GIC), whereas high compliance was more prevalent in subjects with malnutrition and chewing difficulties and those without GIC.

Compared to other intervention studies with ONS in this setting,[14,18,20] the present population had a higher age and a higher degree of functional impairment, both physically and mentally. Unfortunately, functionally impaired residents are often excluded from research[42] despite the fact that they make up a large share of the nursing home population (89.4% cognitive impairment in this study) and are more often at nutritional risk than residents without physical or mental impairment.[3,43] Since both impairments might also limit regular ONS consumption, the present population was particularly challenging with regard to compliance and support by nursing staff was of crucial importance.

To overcome high volumes as a possible barrier for ONS consumption, leading to low compliance, high left-overs and wastage,[23,27,44] the present study used a new low-volume, nutrient- and energy dense formula (2.4 kcal/ml). The compliance observed with this product was better than (54-68%[14,17-19]) or not much below (86-91%[15,16,20]) those reported in other studies in the same setting, despite a large number of drop-outs during the course of the study that markedly reduced overall compliance. Exclusion of these residents would increase the median compliance to 81%. For comparison of different studies and interpretation of results, it has to be considered that assessment methods, documentation and accuracy, which have great impact on reported compliance, widely vary between the studies,[1,21] and in some studies compliance has not been measured at all.

In this study, documentation and assessment of compliance was very detailed and performed on two levels – on the one hand the nursing staff documentation which enabled a daily estimation of the consumption in quarters for each bottle, and on the other hand the regular visits of the study team who collected all bottles, measured left-overs and thereby also controlled the staff documentation. Apart from enhancing reliability of the compliance data, this procedure also enabled getting a very complete picture about the ONS handling and acceptance of both nursing staff and residents. One main finding of the intense contact to the care personnel during data collection was that support from nursing staff is a very important aspect for a successful intervention; wards with motivated care personnel turned

out to have more study participants with higher compliance whereas in other wards with less convinced staff the opposite - a low compliance - was observed. This supports a previous study reporting that lack of compliance of care personnel resulted in reduced serving of ONS.[31] Time constraints of care personnel administering ONS are a practical problem for adequate care.[32]

In the present study there was a significant correlation of all nutritional parameters except calf circumference with ONS intake, which clearly indicates the close association of compliance with nutritional outcome. To achieve a more distinctive evaluation of compliance, residents of the IG were divided into groups, differentiating between those with high (≥80%), median (<30->80%) and low (≤30%) compliance. Analysis of the intervention effects showed significant differences between these groups regarding the changes of nutritional parameters (tab.9). While the group with a low compliance turned out to resemble the CG that tended to deteriorate in nutritional parameters over 12 weeks, residents with high compliance showed a clear increase of nutritional parameters: 3kg body weight gain, improved BMI by 1.2 kg/m² and increased MNA-SF score by 2 points (tab.9). A comparable effect of compliance on body weight has previously been described in hip fracture patients[33], however, this is the first study showing this association in the nursing home population.

As the overall results of the study are reported on ITT level,[35] and thus include those who completely discontinued ONS consumption, the effects of the intervention are attenuated. However, exclusion of those who stopped ONS consumption (making up the entire low compliance group in this study) results in clear benefits of ONS consumption on nutritional parameters compared to subjects without consumption, which would be desirable for all residents at nutritional risk.

Moreover, the present results show that even a medium compliance (30-80%) leads to markedly less pronounced effects than a high compliance (tab.9, fig.6), which also underscores the role of compliance as an important determinant of the effectiveness of the intervention. Indeed, from figure 6 a ‘dose effect curve’ can be recognized regarding compliance and body weight gain. In residents with high compliance it would be interesting to go beyond the present findings and investigate the possibly better clinical and functional outcomes achievable with a good compliance.

For interpretation of the present results, it also has to be taken into account that seven CG residents continued ONS consumption prescribed by their physicians during the study period, which most likely compromised the magnitude of the difference in outcomes between IG and CG.

A further goal of the present study was to learn more about the possible factors influencing compliance in nursing home residents, which have not been focused so far despite playing a

major role. While factors related to the environment[31,32] and the supplement[23,33,34] have been subject of few previous studies, person-related, individual characteristics of nursing home residents have not been investigated so far. The present study results thus provide some interesting insights with possible implications for nursing practice to enhance the success of nutritional interventions.

First of all, it was shown that presence of malnutrition according to MNA-SF was significantly associated with a higher compliance. An explanation for this might be the obvious poor nutritional status of these residents, which was possibly easy to recognize for nursing staff, leading to appropriate closely monitored ONS use and thereby good compliance. On the contrary, not all subjects with less overt malnutrition might have received the attention they require, resulting in a reduced compliance and possibly subsequent weakened ONS effects in this group. To avoid deterioration of nutritional status it might be important to provide equal support and attention though, as the detrimental effects of malnutrition are difficult to reverse in older people.[45]

Furthermore, we found that residents with chewing difficulties also had a high compliance in the present study. For this group of elderly, liquid food might be easier to consume than solid food and thus a good possibility to allow adequate intake of all essential nutrients and energy.

Immobility, depression and presence of gastrointestinal complaints were related to a low compliance (tab.10). Since immobility may be an indicator of higher dependency on nursing staff assistance, the lower compliance among immobile residents might indicate that the support by the care personnel is a decisive factor to improve compliance. On the other hand, ADLs as direct measure for need of assistance did not show any association with compliance, so probably other factors in context with mobility might also be responsible for a subject's compliance. The low compliance observed in residents with depressive mood might be attributable to a lower appetite in these persons.[22] There are indications that nutritional risk is higher in depressed elderly,[3,6,46] however it is to date not clear if depression is the cause or consequence of malnutrition. Depressive mood might lead to a lack of appetite or motivation, resulting in the observed reduced amount of ONS consumed.

The close relation of GIC with low compliance is in line with previous findings[1] can be well explained; adaptation of the diet or stopping supplementation will be the first attempt for improving any discomfort in the gastrointestinal tract and was also observed in the present study. However, documentation of the reasons for discontinuation revealed that in only two cases the study product was reported to be responsible. Thus, many decisions to stop ONS following any feeling of discomfort may have been premature. The present intolerance rate of 5% is markedly below the findings of a recent meta-analysis that reported adverse effects or

tolerance problems in up to 28% in 12 analysed studies with energy- and protein supplementation in elderly that investigated this aspect.[1] In the present study, most drop-out cases were explained by various other factors than the ONS itself. For an even more exact analysis in future trials it would be important to assess the occurrence of discomfort also in the control group.

Interestingly, subjects with a lower number of medications per day were significantly more often not compliant. Considering the possible appetite suppression caused by many medications, this seems to be counter-intuitive and cannot be explained.

In addition, surprisingly, severe cognitive impairment was neither related to low nor high compliance although one might have expected that demented residents are mostly less compliant due to various factors, e.g. comprehension deficits, appetite loss or forgetfulness.[22,47]

Even though these results require confirmation in future trials, for clinical practice it might be of value to alert and train nursing staff with regard to ONS intervention in general, and on certain groups such as immobile or depressed residents in particular. These functionally impaired subjects might be in need of extra assistance to achieve a satisfying compliance level. Additionally, it seems to be important to attempt to solve gastrointestinal complaints individually, and adapt amount and timing of ONS provision instead of immediately deciding to terminate intervention as first measure, to avoid discontinuation of ONS consumption due to discomfort which is often not directly ascribable to the product.

Limitations of the present study were first of all that it was not blinded or placebo-controlled, which, however, is very difficult in nutritional intervention studies. Furthermore, the design and results provide no information on the comparison to standard higher volume ONS as the CG received usual care, which would be interesting to investigate in future trials. It also has to be taken into account that results in clinical practice might deviate from those gained under trial conditions with a special focus on compliance. Although it was important to also include residents with physical or mental impairment for generalizability of results, this also resulted in disadvantages. As a large part of the IG (83%) suffered from severe cognitive impairment and thereby often had limited verbal abilities, it was unfortunately not possible to investigate the palatability of the ONS and its possible impact on compliance. Besides, it also reduced the possibility to adapt feeding regimes or ONS flavours to enhance compliance during the study. Even though nursing staff were instructed to change flavour variants, mode and time of ONS offering whenever low compliance was observed, it is not clear if this suited these residents with positive impact on compliance.

Even though the measurement of compliance was probably more precise than in previous studies, it still offers potential for improvement. Despite a very close contact between the

study team and nursing personnel, it was still difficult to achieve a permanent collection of empty or opened bottles during the weeks with only three visits of the study team. An even more intense training on the wards might have contributed to less missing bottles, which was not completely preventable and therefore a possible inadequacy in the present compliance calculation. However, the documentation on two levels contributed to detect discrepancies to the best possible degree, and thereby led to a very reliable value for compliance, which is an important strength of the present study.

Conclusion

In this randomized, controlled trial, compliance with a low volume, nutrient- and energy dense ONS was generally good, indicating a high acceptance among nursing home residents. High compliance (≥80%) led to significantly greater weight gains and improvements of other nutritional parameters in nursing home residents than low compliance (≤30%) and thus markedly enhanced the effects of ONS. The observed dose-effect relationship underscores the efficacy of ONS supplementation and the results underline the importance of high compliance as determinant for an effective nutritional therapy with ONS. Gastrointestinal complaints, depression and immobility were identified as limiting factors for compliance. Contrary, presence of malnutrition and chewing difficulties contributed to a better compliance to ONS, which may have been mediated by extra assistance given by nursing personnel. To enhance the effectiveness of ONS in clinical practice to a desirable level which has been associated with significant effects in this study, these individual characteristics need to be taken into account by the responsible care personnel when nutritional support with ONS is initiated.

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CHAPTER V

GENERAL DISCUSSION

The present thesis contributes to better knowledge and understanding of a challenging population, characterized by a high degree of functional impairment on both mental and physical level. The screening revealed a high prevalence of nutritional risk, particularly among functionally impaired subjects. Therefore, in contrast to most existing studies in this setting,[1,2] functional impairment was not considered a reason for exclusion which also enhanced the representativeness of the results for current practice. The study has shown significant benefits of nutritional intervention with a low-volume, nutrient- and energy-dense oral nutritional supplement (ONS) in this target group which has not been subject of a controlled intervention trial so far. It is the first study analyzing the important role of compliance in such a level of detail, and demonstrated the considerable impact of the level of compliance on the success of the intervention. But at the same time the findings pointed out several limitations in terms of what improvements one can expect given the poor functional abilities at baseline. Assessment of these functionally impaired residents was linked with various practical difficulties using common methods, further demonstrating the need for a more differentiated approach for this target group.

Screening for malnutrition in nursing home residents

Screening revealed that 64% of the present, very old population showed at least one of the markers of nutritional risk applied in the present study. These results underscore the ongoing relevance that both the presence of malnutrition and the risk for malnutrition have among German nursing home residents. Despite existing guidelines and recommendations from ESPEN[3] and other relevant bodies[4-6] as well as initiatives against malnutrition on both political and international level,[7,8] the high prevalence of nutritional risk identified in the present study indicate that implementation into daily practice remains difficult apparently. Barriers for implementation may derive from lack of knowledge about how to realize regular screenings in daily practice, or about how to transfer the results of a screening in caring routine and initiate nutritional support. In practice, it is important to determine the specific weaknesses and address these accordingly, for example by training of the nursing staff, to improve the situation.

The screening described in chapter two was prerequisite for the subsequent intervention with nutritional support in all residents identified at nutritional risk. This combined approach is important, as both elements build up on each other and cannot be separated. Importantly, we found that the MNA was able to cover almost all residents who also showed one or more of the single nutritional risk markers, which are commonly used in daily practice[6,9] and also

included in guidelines.[3] Compared to the single markers, which identified 11.9-32.9% of residents at nutritional risk, the MNA resulted in 60.2% being malnourished or at risk. This was expectable since all single markers are also part of the MNA and also highlight the wider approach of the MNA that also considers risk factors for malnutrition as acute illness, psychological disorders and immobility, which are otherwise easily neglected despite their negative impact on nutritional status.

For nursing practice, it is important to acknowledge the workload of screening, leading us to the recommendation to use the more concise MNA-SF, which was revised and validated during the time this study took place[10] and represents a practical alternative to the full MNA version used for the screening in the present work. A high sensitivity and specificity with the full version[11,12] makes the short version a reliable, less time-consuming – and therefore more practicable – option for regular screening. Screening for malnutrition should become mandatory upon admission, followed by regular, perhaps quarterly repetition for a constant monitoring of nutritional status, to improve nutritional care and aim for a preventive approach that is a key benefit of the MNA(-SF).[13] However, to avoid overlooking a relatively small number of subjects potentially at risk not identified by MNA, which amounted to 9.6% in the present study, it might be of additional value to also separately look at and evaluate the single risk markers (BMI, intake, weight loss). This only requires little additional effort and provides basic information which is anyway needed for completion of the MNA(-SF). Therefore, the weekly or at least monthly routine assessment of these markers would allow a permanent insight in the development of nutritional status.

Cognitive impairment, depressive symptoms and immobility were often present in screening participants with 59%, 21% and 26%, respectively, and to a higher share found in residents with low MNA, low BMI, low intake or weight loss. Remarkably, the association to functional impairment was consistent for every nutritional risk marker, highlighting that functionally impaired residents face an increased risk for malnutrition, which needs to be considered in daily practice through enhanced attention towards these residents.

Design of the intervention study

As no consensus on a gold standard for screening of malnutrition has been reached yet,[9] and the single markers we assessed during screening are also commonly used, it was decided to apply both the MNA and the single nutritional risk markers as inclusion criteria of the present intervention trial.

Furthermore, all residents with functional impairment were included since the analysis of the screening data underscored that the impaired subjects made up a significant share of all residents affected by nutritional risk. In the present sample this was indicated by different

markers of nutritional risk – not only by MNA, which also contains functional items contributing to the total score, but also by low BMI, low intake and weight loss.

Considering the higher nutritional risk, inclusion of this group for the intervention trial was therefore very important; first, to avoid neglecting any resident who might benefit from nutritional support, and secondly for representativeness of results. This is a clear strength of the study, especially with respect to the fact that many intervention studies with ONS in the nursing home setting excluded residents with dementia and immobility,[14-17] reducing the generalizability of results.[18] On the other hand, inclusion of these impaired residents also led to the difficulty that functional assessment was often hampered by both dementia and immobility. This markedly reduced the number of residents able to perform the functional tests, possibly leading to a reduced significance of results through the resulting lack of power.

For future clinical research it is important to realize that for this target group the fact that proxies need to give consent for participation is a real barrier. Even though screening results often indicated the need for nutritional intervention, a considerable share of affected residents (or their proxies) nevertheless decided not to participate in the subsequent intervention study. This resulted in a comparably low number of study subjects despite both the large sample size at the beginning and a high initial effort for recruitment.

Effects of ONS in nursing home residents

The intervention study presented in chapter three specifically aimed at a broad assessment of outcome parameters – both nutritional and functional – to comply with the current standards of high quality nutrition intervention studies and to fulfill the required minimum dataset.[19]

In line with previous findings of comparable studies[16,20,21] a beneficial effect of ONS on nutritional intake and different markers of nutritional status could be shown. Moreover, the observed trend of deteriorating nutritional status in the control group receiving routine care not necessarily including any measures of nutritional support, also highlights the importance of an early start of nutritional support.

Unfortunately, the positive effect of ONS on various nutritional parameters did however not translate into a concurrent improvement of functionality – these parameters remained stable except for ADLs that significantly decreased in both groups. Even though a direct comparison to previous studies is rather difficult, as most comparable studies excluded cognitively impaired residents,[14,16,20] this was mostly in agreement with the limited number of ONS studies in nursing home residents available.[16,20-22] These also failed to show significant

effects on functional status with exception of one study that combined nutrition intervention with exercise.[14]

There are several factors that need to be taken into account for interpretation of the present results though. First, there are methodical aspects like the statistically correct intention-to-treat approach followed in this study, which included a number of residents in the intervention group who discontinued ONS consumption. This however reduced the overall compliance and probably compromised the effects on outcome. A further factor reducing the difference between the groups might derive from seven subjects in the control group who also received ONS, which was included in the definition of usual care in this study due to ethical reasons, and concurrently highlights the difficulty of performing truly controlled trials in nutrition. Furthermore, the high levels of functional impairment observed at baseline might have reduced the possibility for improvement and limit the expectations of what nutritional support can realistically achieve in this population. It has to be discussed if stabilization of functionality and prevention of further deterioration can already be regarded an intervention success. Besides, functional parameters used in the study may not be completely appropriate; even though recommended for this setting[19] they might in part still lack the sensitivity needed to detect small changes in this population. Tools also need to be feasible for functionally impaired residents who make up a large share in this population. However, at the same time, it needs to be clarified if small changes have relevant implications for daily life. Therefore, the methodology applied in this target group needs further discussion in order to improve research results with regard to functional outcome and its interpretation in this setting.

In this context, quality of life, which was also examined in the present study, is of major importance. It represents another outcome parameter that has seldom been investigated to date in nursing home residents. Therefore and because improvement of an elderly person's well-being is one main goal late in life besides preservation of functionality, this parameter was also assessed in the study. To address the question if an improved nutritional status through supplementation with ONS positively affects quality of life, we used a validated dementia-specific tool (QUALIDEM) specifically designed and validated for the nursing home setting which was applied via interviews with the nursing staff.[23,24] The QUALIDEM is a recommendable tool for future studies as it helps to overcome the problem of quality of life assessment in demented subjects showing cognitive or linguistic difficulties to provide reliable answers, and it proved good overall practicability. The results indicate a positive development in one of the nine investigated quality of life dimensions in the ONS group, which however was different between the groups at baseline. Apart from another category that significantly dropped in the control group there were no differences between the groups for the other dimensions, which underscores the need for further research. Nevertheless, in

context with the before mentioned difficulties in functional assessment, focus on quality of life as key outcome measurement could be worth to think of for future trials. Not only with regard to better assessment but also the higher relevance for the target group for daily life, as improvements in well-being might have a higher impact than, for example, a comparably little gain in strength.

Compliance with low-volume ONS in nursing home residents

The fourth chapter and last manuscript particularly focuses on the compliance of nursing home residents with the novel, low volume ONS used in this study. Even though compliance is one key element for the success of an intervention, studies rarely report this important aspect in detail. Varying accuracy and use of different methodologies to measure compliance in different studies also hamper comparison of results.[2,25] In the present study we precisely measured compliance with documentation on two levels by both nursing staff recording consumed ONS to the nearest quarter and the study team exactly measuring left-overs in ml. This ensured high quality data, and revealed a median compliance of 73%. This result can be regarded as “high” considering that it also included the drop-outs who discontinued ONS consumption during the study period, and it indicates a good acceptance of the new, low volume ONS formula.

Analysis of different compliance groups underscored the considerable positive impact of a high compliance compared to a low compliance with regard to change of nutritional parameters. Even though in a way expectable, these results stress a very important aspect which is often neglected in practice – if a nutritional intervention is initiated it is not only important to provide the ONS, but also very important to closely monitor compliance and support residents with ONS consumption if needed. For the study setting, it is besides of high importance to frequently inform the nursing staff about the ongoing intervention and the different study phases to ensure adequate support in the realization of the study and in particular the intervention.

Analysis of the residents’ characteristics showed that several factors might be indicative for high or low compliance – while immobility, depression and presence of gastrointestinal complaints were associated with low compliance, the presence of malnutrition according to MNA-SF and chewing difficulties were related to high compliance. As this has high practical relevance, these aspects should be studied in more detail in future trials, to ensure that the right conclusions are drawn and to identify further influencing factors that might have a relevant impact on compliance.

Conclusion

In conclusion, the results of the present thesis contribute a number of insights for a better understanding of the nursing home setting and its challenging population, which is, according to our findings, often highly vulnerable and at high nutritional risk. The study addressed different practical aspects and experiences that may be helpful for future research in this population. Besides, the present data set can also contribute input for future meta-analyses needed in this setting.

The observed high prevalence of nutritional risk among nursing home residents underlines the urgent need to further develop awareness for the lasting problem of malnutrition and its risk. Moreover, it emphasizes the importance of regular screening in practice as well as the importance of giving clear advice for implementation in daily routine. The identified close relation between functional impairment and nutritional risk, which has not been shown in this clarity so far, highlights the need to sensitize nursing personnel for both nutritional problems and early initiation of intervention, especially in functionally impaired residents. The findings of the intervention trial underscore the efficacy of a novel low volume, nutrient- and energy-dense ONS to improve compromised or vulnerable nutritional status, making this particular supplement a practical measure that should be used more often in routine care to overcome nutritional problems in elderly.

Even though improvement of functionality could not be shown in this study, this aspect deserves further consideration and investigation in future research. Taking into account the practical problems with the different applied assessment methods for functionality in the present population characterized by high cognitive and mobility impairment, it is important to think about more differentiated approaches to investigate intervention effects on functionality in future studies. Besides, it seems appropriate to either consider stabilization of functional status the maximum achievement of nutritional intervention, or to put more focus on quality of life, a main goal late in life, as key outcome measure.

To enhance the success of nutritional interventions in practice, it is of great importance to increase the efforts for achieving a good compliance and to acknowledge certain factors like the present nutritional status, presence of chewing difficulties, gastrointestinal complaints, depression or immobility that may influence compliance.

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APPENDIX

Einr.: WB: Nr: ☐☐☐ **Datum:**I__I__I - I__I__I - I 2 0 __I__I | **T 1-T2**

DATENERHEBUNGEN Checklist

Tabelle mit Auflistung sämtlicher Erhebungen die für jeden Studienteilnehmer vorgesehen sind. Beim Studienstart Ausfüllen der ersten Daten. Im weiteren Verlauf nach jeder Datenerhebung Abhaken des zugehörigen Feldes – wenn Erhebungen nicht möglich sind Ankreuzen von n.m.

	Datum	**Assessment**	
Screening	_____	☐ MNA ☐ Kriterien und Charakterisierung ☐ Ein- und Ausschlusskriterien	
	_____	☐ Einverständnis	
Blutentnahme	_____	☐ Blutparameter	☐ n.m. Grund:_____
1.DE/ Baseline Messungen	_____	☐ Bew.-Charakterisierung (PFK)	☐ n.m.
	_____	☐ Medizinischer Verlauf	☐ n.m.
	_____	☐ Qualidem	☐ n.m.
	_____	☐ ADL	☐ n.m.
	_____	☐ Medikation und Erkrankungen	☐ n.m.
	_____	☐ Gewicht	☐ n.m.
	_____	☐ Größe	☐ n.m.
	_____	☐ Oberarm-/ Wadenumfang	☐ n.m.
	_____	☐ Handkraft	☐ n.m.
	_____	☐ Gehgeschwindigkeit	☐ n.m.
	_____	☐ MMSE	☐ n.m.
	_____	☐ GDS	☐ n.m.
Interventions-phase	Start:_____ Ende: _____	☐ Tag 1 ☐ IG ☐ KG ☐ letzte Tag Woche 12	☐ Abbruch Nach _____ Tagen am _____
2.DE/ Inter-ventionsende	_____	☐ Medizinischer Verlauf	☐ n.m.
	_____	☐ MNA	☐ n.m.
	_____	☐ ADL	☐ n.m.
	_____	☐ Qualidem	☐ n.m.
	_____	☐ Medikation und Erkrankungen	☐ n.m.
	_____	☐ Gewicht	☐ n.m.
	_____	☐ Oberarm-/ Wadenumfang	☐ n.m.
	_____	☐ Handkraft	☐ n.m.
	_____	☐ Gehgeschwindigkeit	☐ n.m.
	_____	☐ MMSE	☐ n.m.
	_____	☐ GDS	☐ n.m.
Mortalität	_____	☐ Bewohner ist verstorben	Todesursache: _____

Einr.: **WB:** **Nr:** ☐☐☐ **Datum:** I__I__I - I__I__I - I 2 0__I__I | **T1**

Charakterisierung des Studienteilnehmers

Einschätzung durch die Pflegefachkraft (PFK)

	Allgemeine Bewohnerdaten				
A1	Status	O ledig	O verheiratet	O verwitwed	O geschieden O k. A.
A2	Bildungsstand	O Studium	O Ausbildung	O keine Ausbild.	O k. A.
A3	Pflegestufe	O keine	O beantragt	O I O II	O III
	Allgemeinbefinden				
A4	Teilnahmslosigkeit	O wach	O teilnahmslos/ somnolent	O komatös	O k. A.
A5	Ist der Bewohner oft traurig/ niedergeschlagen?	O ja	O manchmal	O nein O weiß nicht	O k. A.
A6	Lebenswille des Bewohners	O Lebensfreude erkennbar		O möchte sterben	
		O indifferent		O k. A.	
A7	Belastende Ereignisse in letzter Zeit (3 Monate)	O ja	O nein		O k. A.
		Art: _____			
A8	Häufigkeit von Besuch	O täglich	O mehrmals wöchentlich		O wöchentlich
		O seltener	O fast nie	O nie	O k. A.
	Moblilität und Aktivität				
A9	subjektive Einschätzung	O hyperaktiv	O sehr aktiv		O mäßig aktiv
		O wenig aktiv	O nicht aktiv		O k.A.
A10	Mobilität	O selbstständiges Fortbewegen möglich (mit/ ohne Hilfsmittel)			
		O Fortbewegung mit Hilfsperson möglich			
		O kann selbstständig mit Rollstuhl fahren (rollstuhlmobil)			
		O immobil sitzend (max. in den Stuhl mobilisierbar)			
		O keine Mobilisation = bettlägerig			
		O k. A.			
A11	Bewegung	O liegt im Bett		O im ganzen Heim unterwegs	
		O sitzt im Stuhl		O geht außer Haus	
		O geht/ fährt im WB umher		O k. A.	
A12	Verlassen des Heimes (Einkaufen, Spazierengehen, Besuche, Garten)	O alleine		O nur in Begleitung	
		O nein		O k.A.	
A13	Wie oft verlässt der Bewohner das Heim?	O täglich	O mehrmals wöchentlich		O wöchentlich
		O mehrmals monatlich	O monatlich	O nie	O k.A.
A14	zusätzliches Training	O täglich	O mehrmals wöchentl.	O wöchentl.	O nie O k.A.
A15	Art des Trainings O irrelev.	O Gymnastik	O Kraftraining		O Koordination
	Ort der Mahlzeiteneinnahme				
A16	Frühstück	O Zimmer	O Wohnbereich		O Speisesaal
A17	Mittagessen	O Zimmer	O Wohnbereich		O Speisesaal
A18	Abendessen	O Zimmer	O Wohnbereich		O Speisesaal
	Ernährung				
A19	Kaubeschwerden/Kaustörung	O ja	O nein	O k. A.	
A20	Schluckstörung	O ja	O nein	O k. A.	
A21	Zwischenmahlzeiten/ Tag (mehrfach Nennung möglich)	1.O Vormittag	2.O Nachmittag	3.O Abend	4.O keine
		5.O Sonstige: _____			6.O k. A.
A22	Kostform	O Standardkost (normale Heimverpflegung)			
		O pürierte Kost (stark zerkleinert)			
		O angereicherte Kost (protein- od. energieangereicherte			
		O Spezialdiäten (Diabetesdiät, purin- oder salzarme Kost)			
		O Sonstige: _____			O k. A

A23	Appetit	O gut	O mäßig	O schlecht	O weiß nicht	O k. A.
A24	Hat sich der Appetit in letzten Wochen verschlechtert?	O ja	O nein	O weiß nicht	O k. A.
A25	Geringe Essmenge	O ja	O nein	O k. A.
A26	Geringe Trinkmenge	O ja	O nein	O k. A.
A27	Mögliche Erklärung für geringe Nahrungs-/ Trinkmenge des Bewohners O irrelev. (mehrfach Nennung möglich)	1.O es schmeckt ihm nicht 2.O Schwierigkeiten beim Essen 3.O ist depressiv 4.O ist dement 5.O Appetitlosigkeit		6. O kein Interesse am Essen 7. O gesättigt durch Zwischenm. 8. O möchte Sterben 9. O Sonstige: _____ 10.O k. A.	
	Ernährungstherapie				
A28	Einnahme v. Trinknahrung	O ja **aktuell** seit: __ __ /__ __ /__ __ - Art/ Name d. Trinknahrung: _____ - Anzahl der Flaschen/ Tag: _____ O bis vor kurzem O nein			O k. A
A29	energiereiche Snacks/ Drinks	O ja	O nein	O k. A.
		seit:__ __ /__ __ /__ __ ; Art: _____			
A30	Probleme bei Verzehr der verschriebenen Menge O irrelev.	O ja	O nein	O k. A.
A31	Vitamine	O ja Art: _____	O nein	O k. A.
A32	Mineralstoffe	O ja Art: _____	O nein	O k. A.
A33	Sonstige	O ja Art: _____	O nein	O k. A.
	Chronische Erkrankungen - Leidet der Bewohner unter...				
A34	...Diabetes	1. O ja (O Typ I O Typ II)	O nein	O k. A.
		2. Medikation: O Insulin O Antidiabetika (Tabletten) O keine			
		Arzt: _____	Tel: _____		
A35	...Dekubitus (Grade nach Seiler)	O ja	O Grad I (Rötung) O Grad II (Hautdefekt) O Grad III (tiefer Hautdefekt) O Grad IV (mit Knochenbeteiligung)	O nein O k. A.
A36	...Wundheilungsstörungen	O ja	O nein	O k. A.
A37	...Exikkose (Austrocknung)	O ja	O nein	O k. A.
A38	...Ödemen (Wassereinlagerung)	O ja	O nein	O k. A.
A39	...Hautveränderungen	O ja	O nein	O k. A.
A40	...Verdauungsproblemen	O ja	O Obstipation O Diarrhöen O Sonstige: _____	O Übelkeit O Erbrechen	O nein O k. A.
A41	... Schmerzen (mehrfach Nennung möglich)	O ja	O Knie O Rücken O Schulter O Sonstige: _____	O Fußgelenk O Ellbogen	O nein O k. A.
A42	Häufigkeit der Schmerzen O irrelev.	O täglich O anfallsweise		O 1x/ Woche O ab und zu	O 1x/ Monat O andauernd
	Interview mit : _____		Position: _____		
	Ausgefüllt von : _____				

Gesundheitszustand (aus Bewohnerakte/ -datei)					
	Medikation				
B1	**Anzahl** verschiedener täglich einzunehmender Medikamente: _____				O k. A.
	1.	6.		11.	
	2.	7.		12	
	3.	8.		13.	
	4.	9.		14.	
	5.	10.		15	
B2	Laxantien	O täglich/ alle 2 Tage	O gelegentlich	O nie	O k. A.
B3	Diuretika	O täglich/ alle 2 Tage	O gelegentlich	O nie	O k. A.
B4	Medik. gegen Inkontinenz	O ja	O nein		O k. A.
B5	Antidepressiva	O ja	O nein		O k. A.
B6	opiathaltige Schmerzmittel	O ja	O nein		O k. A.
B7	Psychopharmaka	O ja	O nein		O k. A.
B8	Medik. gegen Allergien/ Erkältungen (Antihistamine)	O ja	O nein		O k. A.
B9	Medik. gegen Asthma/ COPD (ß-Mimetika)	O ja	O nein		O k. A.
	Chronische Erkrankungen (ärztliche Diagnose)				
B10	Bluthochdruck	O ja	O nein		O k. A.
B11	Herzschwäche	O ja	O nein		O k. A.
B12	Andere Herzkrankheiten:	O ja	O nein		O k. A.
		welche: _____			
B13	Schlaganfall	O ja	O nein		O k. A.
B14	Bösartiger Tumor/Krebs (maligne Grunderkrankung)	O ja	O nein		O k. A.
B15	Schilddrüsenüberfunktion (Hyperthyreose)	O ja	O nein		O k. A.
B16	Schilddrüsenunterfunktion (Hypothyreose)	O ja	O nein		O k. A.
B17	Erkrankung der Atemwege	O ja	O nein		O k. A.
		welche:_____			
B18	Gastritis, Magenerkrankungen	O ja	O nein		O k. A.
B19	Entzündliche Darmkrankheiten	O ja	O nein		O k. A.
B20	Chronische Leberkrankheit	O ja	O nein		O k. A.
B21	Chronische Nierenerkrankung	O ja	O nein		O k. A.
B22	Gelenkserkrankungen	O ja	O nein		O k. A.
	(Arthritis, Rheuma, Arthrose)	welche:_____			
B23	Osteoporose	O ja	O nein		O k. A.
B24	Demenz	O ja	O nein		O k. A.
	diagnost. Form	O Anfangsstadium	O fortgeschrittes Stadium		
B25	O irrelevant	O Sonstige Diagnosen: _____			
B26	Depression	O ja	O nein		O k. A.
B27	Ausmaß	O leicht	O schwer		O k. A.
	O irrelevant				
B28	Weitere Diagnosen:	O ja	O nein		O k. A.

Messungen

Anthropometrie

C1	Methode zum Wiegen	O Personenwaage		O Badelifter	O Hängenetz
		O Hebewaage (mit Rollstuhl)		O Sitzwaage	
		O Sonstige: _____			
	Tageszeit	O Morgens	O Vormittags	O Nachmittags	
C2	Bekleidung	O mit Kleidung	O mit leichter Bekleidung		O ohne Kleidung
C3	Gewicht	___ ___ ___ , ___ kg		Gewicht Rollstuhl:	
		O nicht möglich, da: _____			
C4	Größenmessung	O stehend	O liegend	O Kniehöhe	
C5	Größe	___ , ___ ___ m			
		O nicht möglich, da: _____			
C6	Oberarmumfang	1. O links		O rechts	
		2. __ __ , __ __ cm			
		3. O nicht möglich, da: _____			
C7	Wadenumfang	1. O links		O rechts	
		2. __ __ , __ __ cm			
		3. O nicht möglich, da: _____			
C8	subjektive Einschätzung	O übernährt	O normal	O unternährt	O stark unterern.
C9	Auffälligkeiten	1. Wassereinlagerungen/ Ödeme		O ja O nein	O k. A.
		2. Exsikkose (Austrocknung)		O ja O nein	O k. A.
		3. Kontrakturen		O ja O nein	O k. A.
		4. Sonstiges _____			

Handkraftmessung via Vigorimeter

H1	Durchführung	O möglich	O nicht möglich		
H2	Gründe für fehlende Durchführung	O dement	O fehlende Kooperation		
		O bettlägerig	O sonstige Gründe: _____		
H3	Dominante Hand	O Linkshänder		O Rechtshänder	
H4	Schwierigkeiten bei Messung	O ja		O nein	
H5	welche:	O Arthrose	O Rheuma	O Schmerzen	
		O sonstige Probleme: _____			

		1. Messung:	2. Messung	3. Messung
H9	**Handkraft Messung (kPa):**			

Gehgeschwindigkeit (4 m)

G1	Durchführung	O möglich	O nicht möglich		
G2	Gründe für fehlende Durchführung	O dement	O fehlende Kooperation		
		O bettlägerig	O immobil		
		O sonstige Gründe _____			
G3	Benutzung einer Gehilfe	O ja	O nein		
G4	Art der Gehilfe	O Gehstock	O Begleitung	O leichte Führung/ Stütze	
	O irrelev.	O Rollator		O Sonstige: _____	
G5	Einschränkungen	O ja	O nein		
G6	Art der Einschränkung	_____			
	O irrelev.				
G7	**Zeit für 4 m aus dem Stand gehen**	_____ Sekunden			

Prüfperson : _____

Einr.: **WB:** **Nr:** ☐☐☐ Datum: I__I__I - I__I__I - I 2 0 __I__I | **T 1**

Mini Mental State Examination (MMSE nach Folstein et al.)

O möglich O nicht möglich, da:

O dement O keine Kooperation
O Sonstige Gründe O Schwerhörigkeit
O _____ O Aphasie

	Funktionen		Punkte
I.	**Orientierung -** Können Sie mir sagen…		
1.	Datum		1 / 0
2.	Jahreszeit		1 / 0
3.	Jahr		1 / 0
4.	Wochentag		1 / 0
5.	Monat		1 / 0
6.	Bundesland		1 / 0
7.	Stadt (Landkreis)		1 / 0
8.	Stadtteil (Stadt)		1 / 0
9.	Pflegeheim/ Einrichtung		1 / 0
10.	Wohnbereich/ Stockwerk		1 / 0
II.	**Merkfähigkeit -** Bitte merken Sie sich folgende 3 Begriffe…		
11.	Apfel		1 / 0
12.	Pfennig		1 / 0
13.	Tisch		1 / 0
III.	**Aufmerksamkeit und Rechenfertigkeit -** Bitte ziehen Sie von 100 jeweils 7 ab… (alternativ: "STUHL" rückwärts buchstabieren)		
14.	<93>	(L)	1 / 0
15.	<86>	(H)	1 / 0
16.	<79>	(U)	1 / 0
17.	<72>	(T)	1 / 0
18.	<65>	(S)	1 / 0
IV.	**Erinnerungsfähigkeit -** Wiederholen Sie die 3 genannten Begriffe…		
19.	Apfel		1 / 0
20.	Pfennig		1 / 0
21.	Tisch		1 / 0
V.	**Sprache -** auf Gegenstände zeigen - Was ist…		
22.	Armbanduhr benennen		1 / 0
23.	Bleistift benennen		1 / 0
24.	Nachprechen des Satzes "kein wenn und oder aber"		1 / 0
	Machen Sie bitte Folgendes:		
25.	- Nehmen Sie das Papier in die Hand		1 / 0
26.	- Falten Sie es in der Mitte		1 / 0
27.	- Lassen Sie es auf den Boden fallen		1 / 0
28.	Schriftliche Anweisung befolgen: "Augen zu"		1 / 0
29.	Schreiben Sie bitte irgendeinen (vollständigen) Satz		1 / 0
30.	Überschneidende Fünfecke nachzeichnen		1 / 0

Punkte (von max. 30): _____

Anmerkungen:

Prüfperson:

Einr.: WB: Nr: ☐☐☐ Datum: l__l__l - l__l__l - l 2 0 __l__l | **T 1**

Geriatric Depression Scale (GDS nach Yesavage et al.)

O möglich O nicht möglich, da

O dement O keine Kooperation

O sonstige Gründe: O Schwerhörigkeit

O Aphasie

_____

		(Bitte Ankreuzen)	
1.	Sind Sie grundsätzlich mit Ihrem Leben zufrieden?	O ja (0)	O nein (1)
2.	Haben Sie viele Ihrer Aktivitäten und Interessen aufgegeben?	O ja (1)	O nein (0)
3.	Haben Sie das Gefühl, Ihr Leben sei unausgefüllt?	O ja (1)	O nein (0)
4.	Ist Ihnen oft langweilig?	O ja (1)	O nein (0)
5.	Sind Sie die meiste Zeit guter Laune?	O ja (0)	O nein (1)
6.	Haben Sie manchmal Angst, dass Ihnen etwas Schlimmes zustoßen wird?	O ja (1)	O nein (0)
7.	Fühlen Sie sich die meiste Zeit glücklich?	O ja (0)	O nein (1)
8.	Fühlen Sie sich oft hilflos?	O ja (1)	O nein (0)
9.	Bleiben Sie lieber zu Hause anstatt auszugehen und Neues zu unternehmen?	O ja (1)	O nein (0)
10.	Glauben Sie mehr Probleme mit dem Gedächtnis zu haben als die meisten anderen Menschen?	O ja (1)	O nein (0)
11.	Finden Sie es ist schön jetzt zu leben?	O ja (0)	O nein (1)
12.	Kommen Sie sich in Ihrem jetztigen Zustand ziemlich wert-los vor?	O ja (1)	O nein (0)
13.	Fühlen Sie sich voller Energie?	O ja (0)	O nein (1)
14.	Finden Sie, dass Ihre Situation hoffnungslos ist?	O ja (1)	O nein (0)
15.	Glauben Sie, dass es den meisten Leuten besser geht als Ihnen?	O ja (1)	O nein (0)

Gesamtpunktzahl **/ 15 Punkten**

Anmerkungen:

Prüfperson: _____

Einr.: WB: Nr: ☐☐☐ Datum: I__I__I - I__I__I - I 2 0 __I__I | **T 1**

Aktivitäten des täglichen Lebens (ADL nach Mahoney & Barthel)

Tätigkeiten	*Für **jede Tätigkeit** bitte **eine Einstufung** ankreuzen*		
1. Essen	Selbstständig, benötigt keine Hilfe	10	
	Braucht etwas Hilfe, z.B. beim Schneiden	5	
	Total hilfsbedürtig, unfähig allein zu essen	0	
2. Baden	Selbstständig, benötigt keine Hilfe	5	
	Abhängig von fremder Hilfe	0	
3. Waschen (Rasieren, Kämmen, Zähne putzen)	Selbstständig, benötigt keine Hilfe	5	
	Abhängig von fremder Hilfe	0	
4. An- und Auskleiden	Selbstständig, benötigt keine Hilfe	10	
	Braucht etwas Hilfe, kann aber ca. 50% allein durchführen	5	
	Total hilfsbedürtig, unfähig sich allein an- und auszuziehen	0	
5. Stuhlkontrolle	Kontinent	10	
	Teilweise inkontinent (max. 1x pro Woche)	5	
	Ständig inkontinent	0	
6. Urinkontrolle	Kontinent	10	
	Teilweise inkontinent (max. 1x pro Woche)	5	
	Ständig inkontinent	0	
7. Toiletten-benutzung	Selbstständig, benötigt keine Hilfe bei Toilette/Nachtstuhl	10	
	Benötigt Hilfe für z.B. Gleichgewicht, Kleidung an-/ ausziehen, Toilettenpapier	5	
	Abhängig von fremder Hilfe	0	
8. Bett- bzw. (Roll)-Stuhltransfer	Selbstständig, benötigt keine Hilfe	15	
	Minimale Assistenz oder Beaufsichtigung nötig	10	
	Erhebliche körperliche Hilfe für den Transfer erforderlich, kann Sitzen	5	
	Bettlägerig, abhängig von fremder Hilfe	0	
9. Mobilität	Selbstständiges Gehen für mind. 50 m möglich (Hilfsmittel erlaubt)	15	
	Gehen von mind. 50 m, jedoch nur mit Unterstützung	10	
	Für Rollstuhlfahrer: Unabhängig für mind. 50 m	5	
	Kann sich nicht mind. 50 m fortbewegen	0	
10. Treppen steigen	Selbstständiges Treppensteigen möglich (Gehhilfe erlaubt)	10	
	Benötigt Hilfe/ Überwachung beim Treppensteigen	5	
	Unfähig, alleine Treppen zu steigen	0	

Summe: _____

(von max. 100 Punkten)

Anmerkungen: _____

Interview mit: _____ Ausgefüllt von: _____

Einr.: WB: Nr: ☐☐☐ Datum: I__I__I - I__I__I - I 2 0 __I__I | **T 1**

QUALIDEM zur Erfassung der Lebensqualität (nach Ettema et al.)

	Beschreibung- *zutreffendes bitte Ankreuzen*	**Nie**	**selten**	**manchmal**	**oft**	
	Der Bewohner…					
1.	Ist fröhlich	0	1	2	3	B
2.	Macht ruhelose Bewegungen	3	2	1	0	D
3.	Hat Kontakt mit anderen Bewohnern	0	1	2	3	F
4.	Weist Hilfe der Pflegenden ab	3	2	1	0	A
5.	Hat eine zufriedene Ausstrahlung	0	1	2	3	B
6.	Macht einen ängstlichen Eindruck	3	2	1	0	C
7.	Ist verärgert	3	2	1	0	A
8.	Kann Dinge im täglichen Leben genießen	0	1	2	3	B
9.	Will nicht essen	3	2	1	0	J
10.	Ist gut gelaunt	0	1	2	3	B
11.	Ist traurig	3	2	1	0	C
12.	Reagiert auf Kontaktaufnahme positiv	0	1	2	3	F
13.	Gibt an, dass er/ sie sich langweilt	3	2	1	0	H
14.	Hat Konflikte mit den Pflegenden	3	2	1	0	A
15.	Genießt die Mahlzeit	0	1	2	3	J
16.	Wird von anderen Bewohnern abgewiesen	3	2	1	0	G
17.	Beschuldigt andere	3	2	1	0	A
18.	Sorgt für andere Bewohner	0	1	2	3	F
19.	Ist ruhelos	3	2	1	0	D
20.	Weist Kontakt mit anderen klar zurück	3	2	1	0	G
21.	Hat ein Lächeln um den Mund	0	1	2	3	B
22.	Hat eine angespannte Körpersprache	3	2	1	0	D
23.	Weint	3	2	1	0	C
24.	Schätzt Hilfe, die er/ sie bekommt	0	1	2	3	A
25.	Schottet sich von der Umgebung ab	3	2	1	0	F
26.	Beschäftigt sich ohne die Hilfe anderer	0	1	2	3	I
27.	Gibt an mehr Hilfe zu benötigen	3	2	1	0	E
28.	Gibt an sich eingeschlossen zu fühlen	3	2	1	0	H

	Beschreibung- *zutreffendes bitte Ankreuzen*	**Nie**	**selten**	**manchmal**	**oft**	
	Der Bewohner…					
29.	Ist freundschaftlich mit einem oder mehreren Bewohnern verbunden	0	1	2	3	F
30.	Möchte gern (im Bett) liegen	3	2	1	0	J
31.	Nimmt Hilfe an	0	1	2	3	A
32.	Ruft	3	2	1	0	G
33.	Hat an den Routineabläufen etwas auszusetzen	3	2	1	0	A
34.	Fühlt sich in Gesellschaft mit anderen wohl	0	1	2	3	F
35.	Gibt an nichts zu können	3	2	1	0	E
36.	Fühlt sich im Wohnbereich zu Hause	0	1	2	3	H
37.	Scheint sich selbst wertlos zu fühlen	3	2	1	0	E
38.	Hilft gerne bei Arbeiten im Wohnbereich	0	1	2	3	I
39.	Möchte den Wohnbereich verlassen	3	2	1	0	H
40.	Stimmung lässt sich positiv beeinflussen	0	1	2	3	B

Anmerkungen:

Interview mit: _____

Ausgefüllt von: _____

		Punktebereich		**erreichte Punkte**
A	Pflegebeziehungen (7)	0 - 21	A	
B	Positiver Affekt (6)	0 - 18	B	
C	Negativer Affekt (3)	0 - 9	C	
D	Ruheloses, angespanntes Verhalten (3)	0 - 9	D	
E	Positives Selbstbild (3)	0 - 9	E	
F	Soziale Beziehungen (6)	0 - 18	F	
G	Soziale Isolation (3)	0 - 9	G	
H	Sich zuhause fühlen (4)	0 - 12	H	
I	Etwas zu tun haben (2)	0 - 6	I	
J	Übrige Fragen (3)		J	

NESTLÉ NUTRITION SERVICES

Anamnesebogen zur Bestimmung des Ernährungszustandes älterer Menschen

Mini Nutritional Assessment MNA™

Name: Vorname: Geschlecht: Datum:

Alter, Jahre: Gewicht, kg: Größe, cm: Kniehöhe, cm:
(bestimmen, wenn Körpergröße nicht meßbar ist)

Füllen Sie den Bogen aus, indem Sie die zutreffenden Zahlen in die Kästchen eintragen. Addieren Sie die Zahlen in den ersten 6 Kästchen. Wenn der Wert 11 oder kleiner 11 ist, fahren Sie mit der Anamnese fort, um den Gesamt-Index zu erhalten.

Vor-Anamnese

A Hat der Patient einen verminderten Appetit? Hat er während der letzten 3 Monate wegen Appetitverlust, Verdauungsproblemen, Schwierigkeiten beim Kauen oder Schlucken weniger gegessen (Anorexie)?
0 = schwere Anorexie
1 = leichte Anorexie
2 = keine Anorexie ☐

B Gewichtsverlust in den letzten 3 Monaten
0 = Gewichtsverlust > 3 kg
1 = weiß es nicht
2 = Gewichtsverlust zwischen 1 und 3 kg
3 = kein Gewichtsverlust ☐

C Mobilität / Beweglichkeit
0 = vom Bett zum Stuhl
1 = in der Wohnung mobil
2 = verläßt die Wohnung ☐

D Akute Krankheit oder psychischer Stress während oder letzten 3 Monate?
0 = ja 2 = nein ☐

E Psychische Situation
0 = schwere Demenz oder Depression
1 = leichte Demenz oder Depression
2 = keine Probleme ☐

F Körpermassenindex (Body Mass Index, BMI)
(Körpergewicht / (Körpergröße)², in kg/m²)
0 = BMI < 19
1 = 19 ≤ BMI < 21
2 = 21 ≤ BMI < 23
3 = BMI ≥ 23 ☐

Ergebnis der Vor-Anamnese (max. 14 Punkte) ☐☐

12 Punkte oder mehr: normaler Ernährungszustand

11 Punkte oder weniger: Gefahr der Mangelernährung

Anamnese

G Wohnsituation: Lebt der Patient unabhängig zu Hause?
0 = nein 1 = ja ☐

H Medikamentenkonsum: Nimmt der Patient mehr als 3 Medikamente (pro Tag)?
0 = ja 1 = nein ☐

I Hautprobleme: Schorf oder Druckgeschwüre?
0 = ja 1 = nein ☐

J Mahlzeiten: Wieviele Hauptmahlzeiten ißt der Patient pro Tag? (Frühstück, Mittag- und Abendessen)?
0 = 1 Mahlzeit
1 = 2 Mahlzeiten
2 = 3 Mahlzeiten ☐

K Lebensmittelauswahl: Ißt der Patient
- mindestens einmal pro Tag Milchprodukte? ja ☐ nein ☐
- mindestens ein- bis zweimal pro Woche Hülsenfrüchte oder Eier? ja ☐ nein ☐
- jeden Tag Fleisch, Fisch oder Geflügel ja ☐ nein ☐

0.0 = wenn 0 oder 1 mal «ja»
0.5 = wenn 2 mal «ja»
1.0 = wenn 3 mal «ja» ☐.☐

L Ißt der Patient mindestens zweimal pro Tag Obst oder Gemüse?
0 = nein 1 = ja ☐

M Wieviel trinkt der Patient pro Tag? (Wasser, Saft, Kaffee, Tee, Wein, Bier…)
0.0 = weniger als 3 Gläser / Tassen
0.5 = 3 bis 5 Gläser / Tassen
1.0 = mehr als 5 Gläser / Tassen ☐.☐

N Essensaufnahme mit / ohne Hilfe
0 = braucht Hilfe beim Essen
1 = ißt ohne Hilfe, aber mit Schwierigkeiten
2 = ißt ohne Hilfe, keine Schwierigkeiten ☐

O Glaubt der Patient, daß er gut ernährt ist?
0 = schwerwiegende Unter-/Mangelernährung
1 = weiß es nicht oder leichte Unter-/Mangelernährung
2 = gut ernährt ☐

P Im Vergleich mit gleichaltrigen Personen schätzt der Patient seinen Gesundheitszustand folgendermaßen ein:
0.0 = schlechter
0.5 = weiß es nicht
1.0 = gleich gut
2.0 = besser ☐.☐

Q Oberarmumfang (OAU in cm)
0.0 = OAU < 21
0.5 = 21 ≤ OAU ≤ 22
1.0 = OAU > 22 ☐.☐

R Wadenumfang (WU in cm)
0 = WU < 31 1 = WU ≥ 31 ☐

Anamnese (max. 16 Punkte) ☐☐.☐

Ergebnis der Vor-Anamnese ☐☐

Gesamt-Index (max. 30 Punkte) ☐☐.☐

Auswertung des Gesamt-Index

17-23.5 Punkte Risikobereich für Unterernährung ☐

Weniger als 17 Punkte schlechter Ernährungszustand ☐

Ref.: Guigoz Y, Vellas B and Garry P.J. 1994. Mini Nutritional Assessment: A practical assessment tool for grading the nutritional state of elderly patients. *Facts and Research in Gerontology*. Supplement #2: 15-59.
Rubenstein L.Z, Harker J, Guigoz Y and Vellas B. Comprehensive Geriatric Assessment (CGA) and the MNA: An Overview of CGA, Nutritional Assessment, and Development of a Shortened Version of the MNA. In: "Mini Nutritional Assessment (MNA): Research and Practice in the Elderly". Vellas B, Garry P.J and Guigoz Y , editors. Nestlé Nutrition Workshop Series. Clinical & Performance Programme, vol. 1. Karger, Bâle, in press.

Mini Nutritional Assessment
MNA®

Name:		Vorname:		
Geschlecht:	Alter (Jahre):	Gewicht (kg):	Größe (cm):	Datum:

Füllen Sie den Bogen aus, indem Sie die betreffenden Zahlen in die Kästchen eintragen. Addieren Sie die Zahlen, um das Ergebnis der Anamnese zu erhalten.

Anamnese

A Hat die Nahrungsaufnahme während der zurückliegenden 3 Monate aufgrund von Appetitverlust, Verdauungsproblemen, Schwierigkeiten beim Kauen oder Schluckstörungen abgenommen?
0 = schwere Abnahme der Nahrungsaufnahme
1 = leichte Abnahme der Nahrungsaufnahme
2 = keine Abnahme der Nahrungsaufnahme ☐

B Gewichtsverlust in den letzten 3 Monaten
0 = Gewichtsverlust > 3 kg
1 = weiss es nicht
2 = Gewichtsverlust zwischen 1 und 3 kg
3 = kein Gewichtsverlust ☐

C Mobilität
0 = bettlägerig oder in einem Stuhl mobilisiert
1 = in der Lage, sich in der Wohnung zu bewegen
2 = verlässt Wohnung ☐

D Akute Krankheit oder psychischer Stress während der letzten 3 Monate?
0 = ja 2 = nein ☐

E Neuropsychologische Probleme
0 = schwere Demenz oder Depression
1 = leichte Demenz
2 = keine psychologischen Probleme ☐

F1 Körpermassenindex (Body Mass Index, BMI) (Körpergewicht / (Körpergröße^2), in kg/m^2)
0 = BMI <19
1 = 19 ≤ BMI < 21
2 = 21 ≤ BMI < 23
3 = BMI ≥ 23 ☐

WENN KEIN BMI-WERT VORLIEGT, BITTE FRAGE F1 MIT FRAGE F2 ERSETZEN.
WENN FRAGE F1 BEREITS BEANTWORTET WURDE, FRAGE F2 BITTE ÜBERSPRINGEN.

F2 Wadenumfang (WU in cm)
0 = WU<31
3 = WU≥31 ☐

Ergebnis der Anamnese ☐☐
(max. 14 Punkte)

12-14 Punkte:	normaler Ernährungszustand
8-11 Punkte:	Gefahr der Mangelernährung
0-7 Punkte:	Mangelernährung

Für eine tiefergehende Anamnese, bitte die vollständige Version des MNA® ausfüllen, die unter **www.mna-elderly.com** zu finden ist.

Ref. Vellas B, Villars H, Abellan G, et al. *Overview of the MNA® - Its History and Challenges.* J Nutr Health Aging 2006;10:456-465.
Rubenstein LZ, Harker JO, Salva A, Guigoz Y, Vellas B. *Screening for Undernutrition in Geriatric Practice: Developing the Short-Form Mini Nutritional Assessment (MNA-SF).* J. Geront 2001;56A: M366-377.
Guigoz Y. *The Mini-Nutritional Assessment (MNA®) Review of the Literature - What does it tell us?* J Nutr Health Aging 2006; 10:466-487.

Mehr Informationen unter: www.mna-elderly.com

Einr.: WB: Nr: ☐☐☐ Datum: I__I__I - I__I__I - I 2 0__I__I

Auffälligkeiten/ Unverträglichkeiten/ Rückmeldungen

1) Restbestand unverzehrter TN der Wochenration Fortimel Compact des Bewohners: ___ **Flaschen** von wöchentlich 14 Flaschen (täglich 2 Fl.)	
2) Schwierigkeiten beim Verzehr?	☐ Ja ☐ Nein ☐ nicht bekannt
3) mögliche Gründe für Schwierigkeiten? (mehrfach Nennung möglich) ☐ irrelevant	1. ☐ zu viel / zu großes Volumen 2. ☐ schlechter Geschmack 3. ☐ Demenz 4. ☐ ablehnende Haltung 5. ☐ Sonstige Gründe: _____
4) Auftreten Unverträglichkeitsreaktionen?	☐ Ja ☐ Nein Datum / Zeitpunkt: _____ Vergangene Zeit dazwischen bis zum Auftreten: ___ Stunden
5) Art der Unverträglichkeit? ☐ irrelevant	☐ Übelkeit/ Magenschmerzen ☐ Erbrechen ☐ Durchfall ☐ Kopfschmerzen ☐ Verstopfung ☐ trockener Mund ☐ Sonstige Auffälligkeiten:_____

6) Beschreibung der Unverträglichkeit (mehrfach Nennung möglich) ☐ irrelevant	1. ☐ ähnliche Reaktionen vor Studienbeginn - wenn ja wie oft? ____ 2. ☐ Verschlechterung im Studienverlauf 3. ☐ mögliche Gründe der Unverträglichkeit: _____
7) erforderliche Maßnahmen? ☐ irrelevant	☐ Einsatz von Medikamenten ☐ Arztbesuch ☐ Tage im Bett durch Krankheit
8) Auftreten kritischer Unverträglichkeits-reaktionen mit Komplikationen?	☐ Ja ☐ Nein Art der Komplikationen: _____ Wenn ja: ☐ Arztkontakt ☐ Krankenhausbesuch ☐ Folgeschäden
9) Zusammenhang mit Produkt ☐ irrelevant	☐ definitiv ☐ wahrscheinlich ☐ eher unwahrscheinlich ☐ möglicher Zusammenhang ☐ kann ausgeschlossen werden ☐ weiß nicht/ k. A.
10) Rückmeldung/ Meinung zu Trinknahrungsgabe von Pflegepersonal	☐ ja ☐ Nein

Einr.: WB: Nr: ☐☐☐ Datum: I__I__I - I__I__I - I 2 0__I__I

Messung der unverzehrten Reste Fortimel Compact – Woche 2- 10 (3 x wöchentlich Kontrolle)

Datum (dd/mm/yyyy)	Unverzehrte TN Anzahl der Flaschen	Verzehrte Menge Komplett REST	 Leere Flaschen & Anmerkung
Tag 1 I__I__I - I__I__I - I__I__I__I__I		1. _____ml 2. _____ml 3. _____ml 4. _____ml	
Tag 2 I__I__I - I__I__I - I__I__I__I__I		1. _____ml 2. _____ml 3. _____ml 4. _____ml	
Tag 3 I__I__I - I__I__I - I__I__I__I__I		1. _____ml 2. _____ml 3. _____ml 4. _____ml	

Datum (dd/mm/yyyy)	Unverzehrte TN Anzahl der Flaschen	Verzehrte Menge Komplett REST	 Leere Flaschen & Anmerkung
Tag 1 I__I__I - I__I__I - I__I__I__I__I		1. _____ml 2. _____ml 3. _____ml 4. _____ml	
Tag 2 I__I__I - I__I__I - I__I__I__I__I		1. _____ml 2. _____ml 3. _____ml 4. _____ml	
Tag 3 I__I__I - I__I__I - I__I__I__I__I		1. _____ml 2. _____ml 3. _____ml 4. _____ml	

Einr.: WB: Nr: ☐ ☐ ☐ Datum: : I__I__I - I__I__I - I 2 0__I__I

Bitte **täglich VERZEHRSMENGE** Ankreuzen - **Täglich 2 Flaschen Fortimel Compact**: 1 x vormittags und 1 x nachmittags/abends

Datum	**Zeitpunkt des Verzehrs** der 2 Flaschen Fortimel Compact	**Verzehrte Menge** Fortimel Compact					**Geschmacksrichtung** (Ankreuzen)			
	(Morgen/Nachmittag/ Abend)	**Ganz**	**Dreiviertel**	**Halb**	**Viertel**	**Verweigert**	**Vanille**	**Banane**	**Cappuccino**	**Erdbeere**
	Vormittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Nachmittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Abend	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Vormittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Nachmittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Abend	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Vormittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Nachmittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Abend	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Vormittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Nachmittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Abend	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Vormittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Nachmittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Abend	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Vormittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Nachmittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Abend	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Vormittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Nachmittag	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐
	Abend	1 ☐	3/4 ☐	1/2 ☐	1/4 ☐	V ☐	☐	☐	☐	☐

- Hatte der Proband diese Woche Unverträglichkeiten durch die Trinknahrung? ☐ Ja ☐ Nein

Falls Ja, welche? ☐ Übelkeit ☐ Erbrechen ☐ Durchfall ☐ Sonstige Auffälligkeiten: ____________________

- Mögliche Gründe/Anmerkungen bei geringem Verzehr während der Woche: ____________________

PUBLICATION LIST

ORIGINAL PUBLICATION

Stange I, Pöschl K, Sieber CC, Stehle P, Volkert D: Screening for malnutrition in nursing home residents: Comparison of different risk markers and their association to functional impairment. Journal of Nutrition Health and Aging (JNHA), 2013;17:357-363.

SUBMITTED ORIGINAL PUBLICATION UNDER REVIEW

Stange I, Bartram M, Liao Y, Pöschl K, Kolpatzik S, Sieber CC, Stehle P, Volkert D: Effects of a low volume, nutrient- and energy-dense oral nutritional supplement on nutritional and functional status: a randomized, controlled trial in nursing home residents. Submitted to the Journal of American Medical Directors (JAMDA), Feb. 2013.

PRESENTED AND PUBLISHED CONTRIBUTIONS FOR SCIENTIFIC MEETINGS

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber CC, Volkert D: Impact of oral nutritional supplements on nutritional and functional status of nursing home residents with malnutrition or at risk. EUGMS Congress, 28.-30. Sept. 2011, Malaga, Spain. European Geriatric Medicine 2011, 2 (Suppl.1): S164. (Abstract, Poster)

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber CC, Volkert D: Oral nutritional supplements and quality of life in nursing home residents with malnutrition or at risk. EUGMS Congress, 28.-30. Sept. 2011, Malaga, Spain. European Geriatric Medicine 2011, 2 (Suppl.1): S163-S164. (Abstract, Poster)

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber CC, Volkert D: Effects of oral nutritional supplements on functionality and quality of life of nursing home residents with malnutrition or at risk. ESPEN Congress, 03.-06. Sept. 2011, Gothenborg, Sweden. Clinical Nutrition Supplements, PP036; Volume 6, Issue 1, 2011, Pages 128. (Abstract, Poster)

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber CC, Volkert D: Low-volume, energy- and nutrient dense oral nutritional supplement improves nutritional status of nursing home residents. ESPEN Congress, 03.-06.Sept. 2011, Gothenborg, Sweden. Clinical Nutrition Supplements, PP035; Volume 6, Issue 1, 2011, Pages 127-128. (Abstract, Poster)

Stange I, Liao Y, Pöschl K, Bartram M, Stehle P, Sieber C.C, Volkert D; Compliance von Pflegeheimbewohnern mit einer energie- und nährstoffreichen Trinknahrung. Ernährung 2011. Gemeinsame Jahrestagung der DGEM, AKE, GESKES und VDOE, 26-28. Juni 2011, Graz. Aktuel Ernaehr Med 2011; 36: 193. (Short communication, Poster, Abstract)

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber C.C, Volkert D; Effekte von Trinknahrung auf Ernährungszustand und Funktionalität von Pflegeheimbewohnern mit Mangelernährung oder Risiko für Mangelernährung. Ernährung 2011. Gemeinsame Jahrestagung der DGEM, AKE, GESKES und VDOE, 26-28. Juni 2011, Graz . Aktuel Ernaehr Med 2011; 36: 193. (Short communication, Poster, Abstract)

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber CC, Volkert D; Effects of oral nutritional supplements on nutritional status and physical function of nursing home residents with malnutrition or at risk of malnutrition. International Academy Nutrition and Aging (IANA) Conference, 14.04.2011, Bologna, Italy. Journal of Nutrition Health & Aging, Volume 14, Issue 4, 2011, Page 316. (Oral presentation, Abstract)

Stange I, Liao Y, Pöschl K, Bartram M, Stehle P, Sieber CC, Volkert D: Compliance von Pflegeheimbewohnern mit einer energie- und nährstoffreichen Trinknahrung. Kongress der Deutschen Gesellschaft für Innere Medizin (DGIM), 30.04.-03.05.2011, Wiesbaden. Der Internist 2011, Suppl.1: 68. (Abstract, Poster)

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber CC, Volkert D; Effekte von Trinknahrung auf Ernährungszustand und Funktionalität von Pflegeheimbewohnern mit Mangelernährung oder Risiko für Mangelernährung. Kongress der Deutschen Gesellschaft für Innere Medizin (DGIM), 30.04.-03.05.2011, Wiesbaden. Der Internist 2011, Suppl.1: 66. (Abstract, Poster)

Stange I, Pöschl K, Kaiser MJ, Diekmann R, Sieber CC, Bauer JM, Stehle P, Volkert D: Die neue MNA-Kurzform zur Identifikation von Mangelernährung bei Pflegeheimbewohnern. Wissenschaftlicher Kongress der Deutschen Gesellschaft für Ernährung (DGE), 16.-18.3.2011, Potsdam. (Abstract, Poster)

Stange I, Bartram M, Liao Y, Pöschl K, Stehle P, Sieber CC, Volkert D: Funktioneller Status von Pflegeheimbewohnern mit Mangelernährung oder Risiko für Mangelernährung. Wissenschaftlicher Kongress der Deutschen Gesellschaft für Ernährung (DGE), 16.-18.3.2011, Potsdam. (Abstract, Poster)

Stange I, Liao Y, Pöschl K, Bartram M, Stehle P, Sieber CC, Volkert D: Compliance von Pflegeheimbewohnern mit einer energie- und nährstoffreichen Trinknahrung. Wissenschaftlicher Kongress der Deutschen Gesellschaft für Ernährung (DGE), 16.-18.3.2011, Potsdam. (Abstract, Poster).

Stange I, Liao Y, Pöschl K, Bartram M, Stehle P, Sieber CC, Volkert D: Compliance von Pflegeheimbewohnern mit einer energie- und nährstoffreichen Trinknahrung. DGG Kongress, 16.-18.09.2010, Potsdam. European Journal of Geriatrics, Volume 12, Issue 4, 2010, Page 228. (Abstract, Poster)

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Stange I, Pöschl K, Kaiser R, Sieber CC, Volkert D: Identification of nursing home residents suitable for a nutrition intervention trial. ESPEN Congress, 6.-10.Sept. 2010, Nice, France. Clinical Nutrition Supplements, Volume 5, Issue 2, 2010, Page 12. (Abstract, Poster)

Stange I, Liao Y, Pöschl K, Bartram M, Sieber CC, Volkert D: Compliance of nursing home residents with a nutrient and energy-dense nutritional supplement. ESPEN Congress, 6.-10.Sept. 2010, Nice, France. Clinical Nutrition Supplements, Volume 5, Issue 2, 2010, Pages 124-125. (outstanding Abstract, Poster)

Stange I, Pöschl K, Kaiser MJ, Kaiser R, Sieber CC, Bauer JM, Stehle P, Volkert D: The new MNA-Short Form for the identification of malnutrition in nursing home residents. ESPEN Congress, 6.-10. Sept. 2010, Nice, France. Clinical Nutrition Supplements, Volume 5, Issue 2, 2010, Page 207. (Abstract, Poster)

Stange I, Pöschl K, Kaiser R, Sieber CC, Volkert D: Identifikation von Pflegeheimbewohnern mit Risiko für Mangelernährung als Grundlage einer Intervention mit Trinknahrung. Ernährung 2010. Gemeinsame Jahrestagung der DGEM, AKE, GESKES und VDOE, 17-19. Juni 2010, Leipzig. Aktuel Ernaehr Med 2010; 3: 139. (Abstract, Poster, Oral presentation)

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