

EFFECTIVENESS OF NUTRITIONAL INTERVENTION LED BY CLINICAL DIETITIAN IN PATIENTS AT RISK OF MALNUTRITION AT THE PRIMARY HEALTHCARE LEVEL IN SLOVENIA - EVALUATION STUDY

UČINKOVITOST PREHRANSKIH UKREPOV KLINIČNEGA DIETETIKA V OBRAVNAVI PREHRANSKO OGROŽENIH PACIENTOV NA PRIMARNI RAVNI ZDRAVSTVENEGA VARSTVA V SLOVENIJI - EVALVACIJSKA RAZISKAVA

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ABSTRACT

Keywords:

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Clinical dietitians

Introduction: Clinical dietitians play a crucial role in the nutritional support of patients at risk of malnutrition in primary care settings. The study aimed to evaluate the effect of an individualized nutritional intervention on clinically relevant outcomes for patients with chronic disease at nutritional risk.

Methods: A longitudinal evaluation study was conducted in two Slovenian primary health centres. We used pre-test and post-test design. Patients with chronic disease were screened using the Malnutrition Universal Screening Tool and additional risk factors (≥ 70 years and BMI < 22 kg/m²; lower food intake in the last five days). Patients at nutritional risk were referred to a clinical dietitian for individual nutritional intervention. The effect of the nutritional intervention was assessed six months after the patients' first visit with a clinical dietitian.

Results: The sample included 94 patients. Nutritional risk was reduced significantly in high-risk and moderate-risk patients. In a subgroup of patients with a MUST score ≥ 1 (77 patients), body weight, BMI, Fat-Free Mass Index (FFMI), energy intake, and protein intake increased significantly ($p < 0.001$). At the same time, the phase angle significantly increased ($p < 0.001$), but there were no statistically significant changes in the improvement of grip strength. In a subgroup of patients with MUST score 0 (17 patients), we observed an increase in their median daily energy intake ($p < 0.001$) and median protein intake ($p = 0.003$).

Conclusion: Nutritional intervention delivered by a clinical dietitian improved patients' nutritional intake and nutritional and functional status.

IZVLEČEK

Ključne besede:

prehransko presejanje
prehranski pregled
kronične bolezni
prehranska obravnava
primarno zdravstvo
antropometrične meritve
klinični dietetiki

Namen: Preveriti učinkovitost individualnih prehranskih ukrepov, ki jih v obravnavi prehransko ogroženih pacientov s kronično boleznijo, načrtuje in izvaja klinični dietetik ter se odražajo v spremembah prehranskega in funkcionalnega stanja pacientov.

Metode: Longitudinalno evalvacijsko raziskavo smo med majem 2020 in novembrom 2022 izvedli v dveh večjih slovenskih zdravstvenih domovih. Prehransko presejanje smo izvedli z uporabo univerzalnega orodja za prehransko presejanje Malnutrition Universal Screening Toll (MUST) in dodatnimi dejavniki tveganja (≥ 70 let in ITM < 22 kg/m²; manjši vnos hrane v zadnjih petih dneh). Prehransko ogrožene paciente smo napotili h kliničnemu dietetiku na individualno prehransko obravnavo. Skupino pacientov smo spremljali v dveh različnih časovnih točkah, uporabili smo dizajn pred postopkom/po postopku. Rezultate smo analizirali po šestih mesecih.

Rezultati: V vzorec smo vključili 94 bolnikov. Prehranska ogroženost se je pri pacientih z visokim in zmernim tveganjem po šestih mesecih znatno zmanjšala. V podskupini pacientov z oceno MUST ≥ 1 (77 pacientov) so se telesna masa, indeks telesne mase, indeks puste mase, količina zaužite energije in količina zaužitih beljakovin znatno povečali ($p < 0,001$). Medtem ko se je fazni kot pomembno povečal ($p < 0,001$), je moč prijema ostala relativno stabilna. V podskupini pacientov z oceno MUST = 0 (17 bolnikov), smo po šestih mesecih opazili porast povprečne količine zaužite energije ($p < 0,001$) in povprečno količino zaužitih beljakovin ($p = 0,003$).

Zaključki: Rezultati raziskave so dokazali, da lahko z individualno naravnanimi prehranskimi ukrepi, ki jih izvaja klinični dietetik, pri prehransko ogroženih pacientih s kronično boleznijo pomembno izboljšamo prehransko in funkcionalno stanje ter zmanjšamo njihovo prehransko ogroženost.

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1 INTRODUCTION

It is now widely recognized that patient malnutrition is one of the most serious problems at all levels of healthcare (1-4). Malnutrition results from inadequate nutrient intake or absorption, leading to unfavourable alterations in body composition, cell mass, decreased physical and mental function, and poor clinical outcomes due to disease (5). Despite the scientific evidence and guidelines, there is a lack of practical implementation of knowledge and as a result, malnutrition often goes unrecognized and untreated (6). Failure to treat malnutrition has negative consequences for patient health and quality of life, as well as negative financial implications for the healthcare system (7-12).

In 2019, Klemenc-Ketis et al. (13) provided the only data available in Slovenia on the prevalence of nutritional risk at the primary healthcare level. Their community-based cross-sectional observational study included a population of 1,641 individuals who did not regularly attend family practice. The study revealed that 13.2% of these patients were identified as being at risk of malnutrition, using the Malnutrition Universal Screening Tool (MUST).

Similar to most European countries, Slovenia lacks the integration of nutritional support for patients at risk of malnutrition and nutritional therapy for malnourished patients into the standard medical treatment of all patients at the primary healthcare level. While professional standards for standardized nutritional care processes do exist, their implementation in clinical practice is still pending (14). The Slovenian Association for Clinical Nutrition, in partnership with the Slovenian National Institute of Public Health and Ministry of Health, has developed a comprehensive clinical pathway for integrated nutritional care across all levels of the healthcare system in Slovenia. However, the pathway is yet to be officially published and adopted nationwide.

Clinical dietitians play a crucial role in providing nutritional support in the primary healthcare setting for patients with chronic diseases who are at risk of malnutrition (15). As part of patients' care, clinical dietitians identify and assess their specific nutritional needs, develop an individualized nutritional plan and provide nutritional counselling. They conduct a comprehensive nutritional assessment of patients' dietary habits, nutrient intake, medical conditions and individual needs. Based on the assessment, they develop a personalized nutrition plan, considering patients' nutrient requirements, food preferences and special dietary restrictions. Dietitians may recommend dietary modifications, such as increasing energy and protein intake, to address patients' nutritional needs and support their optimal health (15, 16).

Strong scientific evidence for the health-related and financial benefits of nutritional therapy exists (17-20). The implementation of nutritional strategies, such as optimising protein and energy intake in individuals prone to disease-related malnutrition, has the potential to enhance both the nutritional intake and overall nutritional well-being of patients. This can in turn mitigate adverse outcomes for patients and society. However, there is a lack of studies that have examined the effect of nutritional interventions delivered by clinical dietitians at the primary healthcare level in patients with chronic diseases who are at risk of malnutrition or have malnutrition (17).

The objective of this study was to assess the effectiveness of personalized nutritional interventions, administered by a clinical dietitian, in managing nutritional risks among patients with chronic diseases. These interventions were implemented within the framework of the proposed clinical nutritional pathway in two primary health centres in Slovenia. Additionally, the study underscores the importance of regulating nutritional care for such patient groups at the primary healthcare level in Slovenia.

2 METHODS AND MATERIALS

2.1 Study design and settings

This was a longitudinal evaluation study, utilising a single group pre- and post-test design. We monitored a cohort of patients at nutritional risk of malnutrition at two distinct points: prior to the nutritional intervention and six months after.

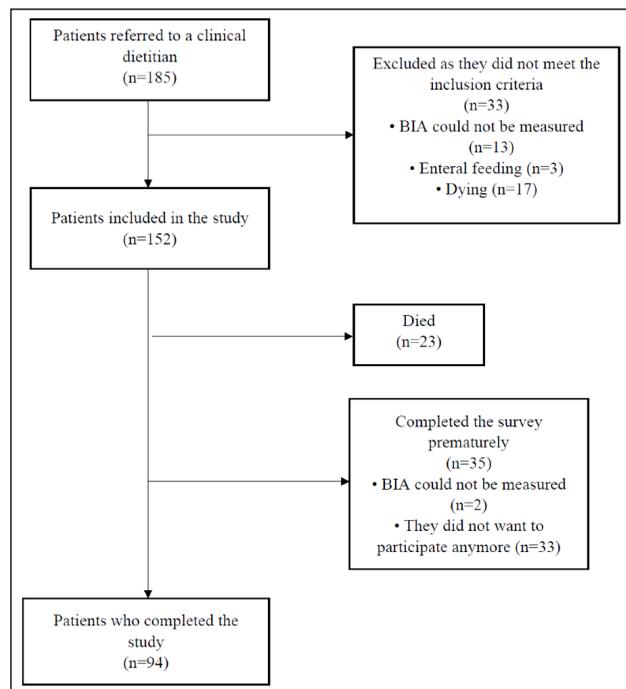
The research was conducted across two primary health centres in Slovenia: a sizable centre in Žalec and medium-sized centre in Celje. The study spanned from May 2020 to November 2022 and was approved by the Commission for Medical Ethics of the Slovenian Ministry of Health (number 0120-472/2020/8).

2.2 Participants

Participants were included in the sample using non-probability (convenience) sampling. The sample consisted of individuals who, throughout the observed period, were identified as being at nutritional risk and received treatment either from a general practitioner (GP) in a primary care physician's office or from a community nurse providing care at the patients' homes. Nutritional risk screening was performed by the GP or a community nurse. Adult patients (>18 years) of both sexes at nutritional risk who agreed to participate in the study and met all inclusion criteria were included in the sample.

The study did not include patients whose body mass and muscle strength could not be measured, dying patients, patients with a proven eating disorder, tube-fed patients and patients with a pacemaker. The number of patients included in the nutritional screening was 185. The number

of patients at nutritional risk who met all inclusion criteria was 152, and a total of 94 participants completed the 6-month examination. The reasons for dropout are described in Figure 1.

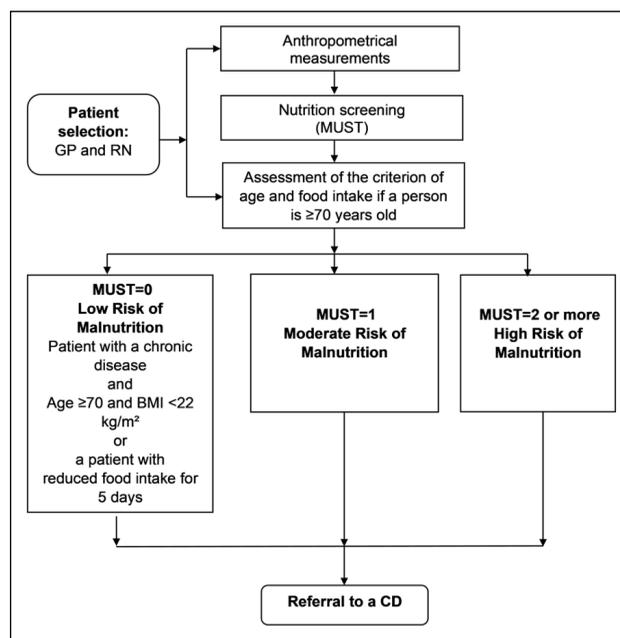


Legend: BIA=bioelectrical impedance analysis

Figure 1. Participants in the nutrition intervention and the reasons for exclusion or dropout from the study.

2.3 Study instruments

The nutrition care process considered all the steps defined in the proposed clinical nutrition pathway (Figure 2). Nutritional risk screening was performed using the established and validated screening tool MUST, which includes three criteria to determine the overall risk of malnutrition: BMI, unintentional weight loss and impact of acute illness. The score obtained for each measure is used to assess the patient's overall level of nutritional risk. A MUST score of 0 indicates a low risk of malnutrition, a MUST score of 1 indicates a moderate risk, and a MUST score of 2 or more indicates a high risk of malnutrition (21-24). Due to limitations of the MUST tool, we included additional criteria in nutritional screening when the MUST score was assessed as 0. These were age ≥ 70 years and BMI < 22 kg/m² with the presence of at least one chronic disease, or the patient had at least one chronic disease and a lower food intake in the last five days (25).



Legend: GP=general practitioner; RN=registered nurse; CD=clinical dietitian; MUST=Malnutrition Universal Screening Tool

Figure 2. Proposed clinical nutrition pathway.

2.4 Study intervention

All patients at nutritional risk were referred to a trained clinical dietitian for individualized nutrition support and counselling. The patients' nutritional support consisted of four sessions - the first visit and three follow-up visits. The first follow-up visit was carried out one month after the first visit, the second three months after and the third one six months after the first visit. Information on the patient's health status was obtained from the patient's medical records and provided to the dietitian by the GP who treated the patient. The clinical dietitian conducted comprehensive assessments, including nutritional intake, anthropometric measurements, body composition analysis and functional evaluations during each visit. In the final session, the clinical dietitian reassessed the nutritional risk with the MUST screening tool. Nutritional counselling, aligned with the principles of the Nutrition Care Process Model (NCPM) (26-28), focused on educating the patients on modifying their dietary intake to meet their energy, macronutrient and micronutrient needs. Following each visit, the clinical dietitian prepared a personalized nutritional plan, providing specific guidance for patients regarding suitable food types and amounts, along with suggestions for fortifying food and meals (e.g. incorporating protein powders and snacks). The plan also outlined the advised frequency of daily meals and specified the required daily energy and protein intake. Oral nutritional supplements (ONS) were offered when a patient's nutritional needs could not be met by a regular diet alone. The plan considered patient preferences,

potential limitations and existing chronic diseases. The main objective of the nutritional intervention in patients with a moderate or high risk of malnutrition ($MUST \geq 1$) was to improve their nutritional and functional status. In low-risk patients ($MUST=0$), the primary aim was to improve their nutritional intake and prevent the increase of their nutritional risk. The overall effect of the nutritional intervention was evaluated six months following the patient's initial visit with a clinical dietitian.

2.5 Nutritional assessment

Clinically relevant patient characteristics, which were measured as baseline data at the first visit and after six months, included nutritional risk score assessed with the MUST tool, a patient's nutritional status determined with anthropometric measures of BW, Body Mass Index (BMI) and body composition measures of Fat-Free Mass (FFM) and Fat-Free Mass Index (FFMI). Body composition was assessed with bioelectrical impedance analysis (BIA) using Bodystat Quadscan 4000. Muscle function was evaluated with phase angle (PA), measured with BIA, and hand grip strength, measured with a Baseline hydraulic hand dynamometer following the Southampton protocol (29). Nutritional intake was assessed with the patient's daily energy intake (kcal/d) and daily energy intake per kilogram of total body mass (kcal/kg TM). Protein intake was assessed with the patient's daily protein intake per kilogram of total mass (P/kg TM). Nutritional intake was assessed using a 24-hour retrospective recall method and a checklist of specific foods and beverages to verify food intake reported by patients and evaluated using the Prodi® 6 Expert programme (<https://www.nutri-science.de/software/prodi.php>).

Patients' nutritional intakes were estimated according to the most recent ESPEN guidelines for patients with various chronic diseases (30-35). A daily energy requirement of 30-35 kcal/kg TM and a daily protein intake of 1.2-1.5 g/kg TM was recommended for all patients, except for lower protein intake for patients with chronic renal insufficiency of 0.8 g/kg TM (36).

2.6 Statistical analysis

Data collection, visualization and statistical analyses were performed using R 4.2.1 version. Descriptive statistics were calculated, and all continuous data were expressed as a mean, median and standard deviation of the mean, minimum and maximum values. The categorical data were expressed as frequencies and percentages. The Kolmogorov-Smirnov test was carried out to test the normality of the continuous variables. Differences in measurements of nutritional status, nutritional intake and functional status before and after intervention were tested using the exact Wilcoxon signed-rank test (EWSRT). The significance level was set to 0.05.

3 RESULTS

3.1 Study participants

The baseline social demographic and clinical characteristics are described in Table 1.

Table 1. Baseline characteristics of the sample.

Characteristics	Values (n=94)
Basic variables	
Female	59 (63%)
Male	35 (37%)
Age, y	68 [15] (20- 92)
Living conditions	
Alone	21 (22%)
Community (family)	31 (33%)
With partner	42 (45%)
Comorbidities	
Cardiovascular diseases (including CAF)	37 (39%)
Pulmonary diseases	4 (4%)
Diabetes and other endocrine diseases	12 (13%)
Kidney diseases	4 (4%)
Gastrointestinal diseases	26 (28%)
Diseases of the liver and pancreas	3 (3%)
Oncological diagnoses	29 (31%)
Wounds	2 (2%)
Neurological diseases	6 (6%)
Rheumatological diseases	2 (2%)
COVID-19	2 (2%)
Other	13 (14%)

Note: Values are mean [SD] (minimum-maximum) for normally distributed continuous data and n (%) for categorical data
Legend: y=years, CAF=Chronical Atrial Fibrillation, COVID-19=Coronavirus Disease 2019

Among 94 patients participating in the study, 55 (59%) had one chronic disease, 33 (35%) had two, and 6 (6%) had three or more diseases. The comorbidity distribution based on the MUST risk groups are described in Table 2.

Table 2. Comorbidity distribution based on the risk groups (MUST).

Characteristics	MUST=0		MUST \geq 1	
One comorbidity	9	53%	46	60%
Two comorbidities	7	41%	26	34%
Three or more comorbidities	1	6%	5	6%
Total	17	100%	77	100%

Legend: MUST=Malnutrition Universal Screening Tool; MUST=0 indicates patients at low risk of malnutrition, MUST \geq 1 indicates patients with moderate or high risk of malnutrition

3.2 Nutritional risk after six months

An overview of how individuals' risk group categorization changed after 6 months using the MUST tool is presented in Table 3. It indicates the percentage of individuals who remained in the same risk category, improved their nutritional status or shifted to a higher risk category.

Table 3. Contingency table showing frequencies and proportions of patients based on the risk groups (MUST) at the beginning and after six months.

MUST score at the beginning	MUST score after 6 months			
	0	1	≥2	SUM
0	16 94%	0 0%	1 6%	17 100%
1	25 83%	4 13%	1 3%	30 100%
≥2	27 57%	12 26%	8 17%	47 100%

Legend: MUS=Malnutrition Screening Tool

Table 4. Comparison of changes in nutritional status, nutritional intake and functional status in a subgroup of patients with MUST≥1 (n=77).

Nutritional status values	1st assessment	2nd assessment	3rd assessment	4th assessment	Improvement (p value*)
BM (kg)	60.9 (56.50) [14.9] (39.1, 100.0)	60.9 (56.50) [14.9] (39.1, 100.0)	63.3 (59.0) [15.4] (39.5, 102.3)	64.0 (60.0) [15.3] (40.0, 103.7)	<0.001
BMI (kg/m ²)	22.0 (20.7) [4.9] (14.5, 41.1)	22.0 (20.7) [4.9] (14.5, 41.1)	22.8 (21.3) [4.8] (14.1, 39.0)	23.1 (21.9) [4.7] (14.3, 39.0)	<0.001
FFM (kg)	41.5 (38.6) [11.4] (19.8, 73.0)	41.5 (38.6) [11.4] (19.8, 73.0)	42.7 (39.7) [11.8] (20.2, 77.2)	42.8 (39.2) [11.7] (20.4, 76.1)	<0.001
FFMI (kg/m ²)	14.8 (14.5) [3.0] (9.2, 22.5)	14.8 (14.5) [3.0] (9.2, 22.5)	15.3 (14.8) [3.0] (7.9, 23.8)	15.3 (14.8) [3.0] (8.1, 23.5)	<0.001
Nutritional intake					
Energy (kcal/kg TM)	20.7 (20.3) [7.6] (5.6, 41.0)	20.7 (20.3) [7.6] (5.6, 41.0)	28.1 (28.7) [7.7] (3.1, 46.7)	30.3 (30.0) [7.1] (13.3, 53.3)	<0.001
Energy (kcal/d)	1217 (1121) [415] (369, 2339)	1217 (1121) [415] (369, 2339)	1722 (1744) [438] (155, 3176)	1876 (1945) [377] (850, 2749)	<0.001
Protein (g/kg TM)	0.9 (0.9) [0.4] (0.1, 2.3)	0.9 (0.9) [0.4] (0.1, 2.3)	1.3 (1.3) [0.4] (0.3, 2.6)	1.4 (1.4) [0.4] (0.5, 2.5)	<0.001
Functional status					
PA (°)	4.7 (4.7) [1.0] (2.4, 7.6)	4.7 (4.7) [1.0] (2.4, 7.6)	5.0 (4.9) [1.0] (2.5, 8.8)	5.0 (4.9) [0.9] (2.8, 7.5)	<0.001
Grip strength (kg)	24 (23) [11] (1, 62)	24 (23) [11] (1, 62)	26 (24) [12] (1, 64)	26 (24) [12] (1, 64)	0.080

Note: Values are mean (median) [SD] (minimum-maximum). *Wilcoxon signed rank test.

Legend: BM=Body Mass, BMI=Body Mass Index, FFM=Fat-Free Mass, FFMI=Fat-Free Mass Index, TM=Total Body Mass, kcal/kg TM=energy intake per kilogram of total body mass, kcal/d=daily energy intake, g/kg TM=daily protein intake per kilogram of total mass, PA=Phase Angle

3.3 Nutritional status, functional status and nutritional intake

Patients with MUST≥1 (77 patients) were included in the analysis of all changes in their nutritional status, nutritional intake, and functional status. The results are presented in Table 4.

In patients with MUST score of 0, we observed a statistically significant change after six months, as their median daily energy intake increased from 1303 kcal/d to 1990 kcal/d (p<0.001), median energy intake per kilogram of total mass increased from 18.5 kcal/kg TM to 28.0 kcal/kg TM (p<0.001), and protein intake also significantly increased from 0.8 g P/kg TM to 1.2 g P/kg TM (p=0.003).

4 DISCUSSION

In this six-month intervention study, we demonstrated the positive outcomes resulting from the nutritional interventions delivered by a clinical dietitian to patients with chronic diseases at risk of malnutrition. These interventions followed the principles of NCPM (26, 27) and were integrated into the proposed nutrition pathway (Figure 1).

In a subgroup of patients with a $MUST \geq 1$ (77 patients), the data show significant improvements in patients' nutritional intake and nutritional status. Additionally, despite the results of grip strength measurements remaining relatively constant after six months, we found that their functional status, measured with the PA, improved significantly (Table 4). The reduction in nutritional risk was statistically significant for patients initially assessed as having moderate or high risk of malnutrition, whereas low-risk patients exhibited consistent results after the six-month period (Table 3). These findings underscore the critical role of clinical nutritional measures in improving patients' nutritional and functional status and preventing potential deterioration. To our knowledge, this is the first study that confirmed the benefit of dietetic counselling within a primary healthcare system according to systematic clinical nutritional evaluation through a model of the clinical nutritional pathway.

Our findings are also in line with the results of several studies in different clinical settings investigating the impact of nutritional interventions performed by clinical dietitians across various populations of patients with chronic diseases. Notably, the research on individual dietary counselling for cancer patients undergoing oncological treatment revealed a significant reduction in weight loss by the end of the treatment period due to the nutritional intervention (37, 38). The study further demonstrated improved fulfilment of estimated energy and protein requirements during treatment (37), and individuals in the intervention group exhibited a notably enhanced state of nutrition or anabolic status (38).

Incorporating dietitians into the team for continuous care of geriatric patients following hospital discharge has improved patients' body mass (39, 40), energy and protein intake (39). However, as with our results, there was not always a statistical improvement in patients' grip strength (39, 40). Munk et al. (41) evaluated the effects of long-term, individualized nutritional interventions in elderly patients with several chronic diseases at hospital discharge. This intervention focused on optimizing protein intake, with a highlighted emphasis on the importance of strength training. Consistent with prior research (37-40), the patients in their intervention group lost significantly less body mass and experienced a significant increase in energy and protein intake. In addition, an improvement

in physical function, as measured by the chair stand, was observed in the intervention group (41).

Our findings demonstrate that personalized nutritional intervention performed by a clinical dietitian contributes positively to enhancing patients' nutritional intake, nutritional status and phase angle. Importantly, the lack of improvement in hand grip strength highlights the importance of incorporating a strength training programme for this patient cohort.

The recent systematic literature review of 94 separate studies by Baldwin et al. (42) mainly found low-certainty evidence to suggest that dietary advice given with or without ONS may improve nutritional status in adults with disease-related malnutrition or at nutritional risk. While not revealing distinct patterns regarding the optimal timing for nutritional intervention to be effective across the trajectory of patients' diseases, the review indicates the feasibility of achieving increased energy intake and weight gain through dietary advice, with or without oral nutritional supplements (ONS) (42).

The favourable outcomes of our study indicate that the selected clinical approach, within the proposed nutritional pathway, integrated essential aspects of patient nutritional care (14). This proved effective even in an environment where knowledge and awareness regarding malnutrition-related issues are lacking. The nutritional pathway enabled the implementation of clinical guidelines in clinical practice, better planning, a patient-centred approach and implementation of effective nutritional intervention for each patient included in the study.

The study results also indicate that periodical individual nutritional counselling over six months enabled the patients to have frequent enough contact with the clinical dietitian, thus maintaining their motivation and enabling them to accept responsibility for following the set nutritional goals. It can also be inferred that periodic verification of anthropometric measurements and dietary intake was an opportunity for patients to monitor the progress of their nutritional status. Thus, there was greater engagement with the proposed nutritional therapy.

5 LIMITATIONS

The sampling type was convenience, the study was not randomized, and the study included only patients at nutrition risk in two health centres in Slovenia during a specific period, so we should not generalize the results. The primary strength of the study is the high compliance with the nutritional intervention in patients who completed the study, and the major weakness is the high dropout rate of the participants during the study ($n=35$) and patients who died during the study ($n=23$) (Figure 1). We presume that the most likely reason is that this study

was conducted during the sudden onset and widespread of the COVID-19 pandemic's mandated social distancing and quarantines.

6 CONCLUSIONS

Individually oriented nutrition dietary counselling and evaluation performed by a clinical dietitian had a beneficial effect on the patient's nutritional and functional status. The improvement of nutritional status protects patient health and enables better treatment of acute and chronic diseases. Our study confirms that clinical nutrition measures are recommended to be integrated into patients' treatment as a part of precision medicine. Clinical dietitians in primary healthcare settings play a crucial role in the nutritional care of patients with chronic diseases who are at risk of malnutrition. However, clinical dietitians in Slovenia are sparsely available in primary healthcare and are mainly part of health promotion centres that focus on preventive nutrition care for children and adults. Therefore, the results of this research may significantly contribute to understanding the important role of a clinical dietitian in primary care in Slovenia. It also highlights the need for immediate systemic activities: education of clinical dietitians based on international standards, national regulation of their professional profile and their systematization as health workers.

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CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

The study was approved by the Commission for Medical Ethics of the Slovenian Ministry of Health (number 0120-472/2020/8).

AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

LLM STATEMENT

During the preparation of this article the author(s) used the GPT-3.5 language model to:

- review and amend grammatical and spelling mistakes,
- ensure linguistic consistency and coherence,
- test and fine-tune the article's wording,

After using this model, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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