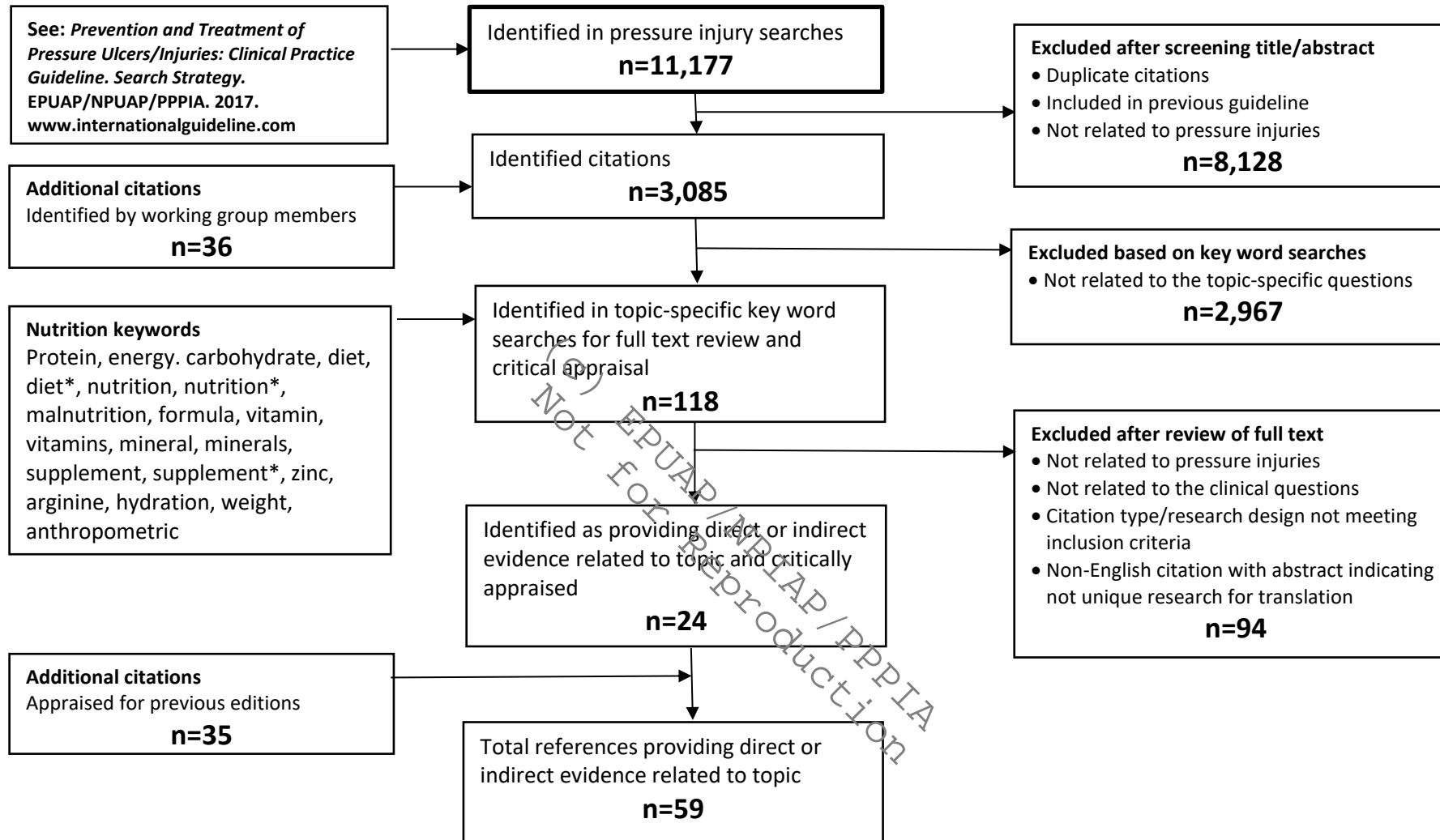


Nutrition: data extraction and appraisals

Search results for 2019 International Pressure Injury Guideline: Nutrition



European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

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Articles Reviewed for International Pressure Injury Guideline

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables have not been professionally edited. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resources and are not for reproduction.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Nutritional screening, assessment and care planning							
Grattaglia no et al., 2017	Cohort study investigating prognostic ability of Mini Nutritional Assessment test to predict pressure injury development	<p>Participants were recruited in 4 general practices in Italy (n=274)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Aged over 75 years <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Terminal illness Cancer Terminal renal failure Recurrent electrolyte imbalance <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 82±5 years 75% male 	Assessment made by GP using MNA at baseline and at 24 months	<ul style="list-style-type: none"> Nourishment assessed on MNA Categorized as well nourished, at risk of malnutrition and malnourished BMI 	<p>Initial assessment (n=274)</p> <ul style="list-style-type: none"> 63.8% well nourished, 25% at risk of malnourishment, 10.9% malnourished Malnourished individuals were significantly more likely to be on bed rest (p<0.05), have a fracture (p<0.05), be admitted to hospital (p,0.05) <p>Follow up (24 months, n=224)</p> <ul style="list-style-type: none"> 47 participants lost to death Malnourished people were more likely (p<0.05) to have a PU (14.7%) than those who were well nourished (0%) or at risk of malnourishment (0%) Malnourished individuals were significantly more likely to have dementia (p<0.05), have a fracture (p<0.05), be admitted to hospital (p<0.05) or to have died (p<0.05) <p>Psychometric properties</p> <p>MNA cut off score 7 had positive predictive value 0.92 and negative predictive value 0.71</p> <p>Author conclusions: Individuals screened as having malnutrition are more likely to develop a pressure injury.</p>	<ul style="list-style-type: none"> Does not define cut offs for categories of nourishment Unclear what if any nutritional intervention was made at initial assessment 	<p>Level of evidence: 1 (prognostic)</p> <p>Quality: Moderate</p>

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Tsaousi, Stavrou, Ioannidis, Salonikidis, & Kotzampassi, 2015	Observational prevalence survey of under-nutrition and PUs and MUST screening results	All inpatients in a 680-bed hospital in Greece (n=603, n=471 with complete data)	A single day audit recording: Demographics, anthropometric characteristics, diagnosis, quality of health status rated on comorbidities and patients self-perceived health, dietary parameters, BMI, length of stay	Malnutrition Screened using Malnutritional Universal Screening Tool (MUST) with high risk at BMI <18.5, >10% unintentional weight loss in previous 3 to 6 months or n nutritional intake for 5 days Pressure injuries Staged using NPUAP/EPUAP screening tool	PU prevalence rate 14.2% (n=67) Univariate logistic regression for association between pressure injury and nutritional status: <ul style="list-style-type: none"> Age: OR=1.056 (95% CI 1.022 to 1.091, p=0.003) Low BMI (<18.5): OR=7.893 (95% CI 1.783 to 28.932, p=0.003) High BMI (>28): OR=2.861 (95% CI 1.068 to 8.458, p=0.047) MUST at-risk of malnutrition: OR=3.398 (95% CI 1.209 to 9.552, p=0.020) MUST malnourished: OR=7.013 (95% CI 2.152 to 23.506, p=0.007) Recent weight loss: OR=2.356 (95% CI 1.097 to 5.721, p=0.027) Significant findings related to quantity of food consumed and meal types Conclusions: There is an association between nutritional status and developing a pressure injury. There is also an association between MUST screening status and pressure injuries.	<ul style="list-style-type: none"> Method of identifying pressure injuries not reported Does not consider confounders such as medical diagnoses Does not report pressure injuries present on admission versus facility-acquired 	Level of evidence: 3 (prognostic) Quality: Moderate
Yatabe et al., 2013	Prospective cohort study exploring predictive ability of MNA	Consecutive inpatients in a hospital in Japan (n=422) Inclusion criteria: Admitted to intermediate and acute care ward in the study period Exclusion criteria: Existing pressure injury Participant characteristics: Mean follow up period 62.2±86.4	<ul style="list-style-type: none"> NA 	<ul style="list-style-type: none"> MNA Subjective Global Assessment Braden Scale Daily skin assessment to identify PUs using DESIGN-R Analysis included only PUs Category/Stage II or greater Laboratory values 	PU prevalence rate 7.1% MNA predictive ability <ul style="list-style-type: none"> 29/30 participants who developed pressure injury had MNA score < 8 Sensitivity 97%, specificity 42% After adjusting for total protein, albumin, cholinesterase and Triglyceride, MNA was significantly associated with PU development (OR 0.715, 95% CI 0.546 to 0.937, p=0.01) 	<ul style="list-style-type: none"> Few risk factors in MV analysis Follow up for pressure injury development time frame not noted 	Level of evidence: 3 Quality: Low (prognostic)

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Mean age 85 years			Author conclusions MNS has sufficient predictive ability for pressure injuries in older patients		
Meehan et al., 2016	A retrospective cohort study exploring the effect of introducing a nutrition quality improvement team	Retrospective record review conducted in the facility covering a 6-month period pre-QI initiative introduction (n=10,106) and a 6 month period post QI introduction (n=9,761) Inclusion criteria: Aged ≥ 18 years Participant characteristics: Mean age 59 years (range 18 to 111) Patients were classified as nutrition-sensitive if they had one of the top 10 diagnosis requiring ONS and this did not differ between pre (n=1,567) versus post (n=1,574)	<ul style="list-style-type: none"> An interdisciplinary quality improvement team was formed to conduct quality improvement in nutrition delivery services The team developed a system that included nurses screening patient nutritional status on admission using Malnutrition Screening Tool Nurses prescribing oral nutritional support (ONS) for patients at risk of malnutrition ONS prescription electronically linked to medical administration record to cue nurses to deliver and record delivery of ONS 	<ul style="list-style-type: none"> Time from nutritional screening to initiation of the nutritional intervention Use of ONS in at risk patients Hospital acquired PU Cost 	<p>Nutritional interventions</p> <ul style="list-style-type: none"> The QI initiative was associated with reduction in time to receiving ONS from 2.3 days to < 24 hours. Proportion of patients receiving ONS significantly increased post QI intervention (pre 6.1% versus post 8.1%, p<0.01) <p>Hospital acquired PU QI intervention was associated with 50% reduction in HPAU (pre 40 versus post 20)</p> <p>Cost For nutrition-sensitive patients with the top 10 diagnoses associated with requiring ONS, cost of hospitalization decreased significantly (p<0.01) by 8.8%</p> <p>Authors conclusion: An interprofessional QI intervention promoting ONS is associated with reduction in HAPUS</p>	<ul style="list-style-type: none"> Post-measurement was taken about 18 months after intervention introduction to allow nurses to become familiar with process Poor reporting of comparative populations Unclear how PUs were identified and assessed 	<p>Level of evidence: 3</p> <p>Quality: low</p>
Corrales, Gayo, Águila, Martín, & Ribeiro, 2014	Cross-sectional observational study describing nutritional status and its progression throughout admission	Observation was conducted in a long-term care unit in Spain over a 6-month period (n=76) Inclusion and exclusion criteria are not reported, implies all patients admitted were included Participant characteristics:	<ul style="list-style-type: none"> Nutrition screening tool used was the Mini Nutrition Assessment (MNA) to determine malnutrition or risk of malnutrition Nutrition management was not reported, assumed it is routine nutrition 	<ul style="list-style-type: none"> Standard data collected in 24hrs from medical record Barthel Index (assesses disability) and Braden Scale completed at admission and discharge 	<p>Observations</p> <ul style="list-style-type: none"> Braden scale 39% high risk of PI, 22.4% moderate risk and 38.2% slight risk 44.7% had PIs and those with PIs, included 79.4% who were malnourished and 20.6% were at risk for malnutrition Significant relationship between malnutrition screened on MNA and dependence on ADL (p=0.102): individuals screened as having malnutrition also had severe or total dependence and nutrition 	<ul style="list-style-type: none"> No analysis of relationship between MNA and Braden scale or PIs, or any logistic regression to evaluate MNA as a prognostic tool Study could not include all of the many risk factors 	<p>Level of evidence: 4</p> <p>Quality: low</p>

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> • Mean age 78.13±11.31 • Comorbidities included: 21.1% mobility problems; 17.1% respiratory problems; 32% diabetes • 15.8% hip fractures, • 15.8% had pressure injuries of the total cohort • 80.3% had chronic conditions and moderate to high risk for pressure injury development 		<ul style="list-style-type: none"> • MNA used for nutrition with score of ≤17 used as cut off for malnutrition, 17 to 23.5 considered at risk 	<p>and dependence level improved concurrently</p> <p>Conclusion: Authors conclude the need to assess and address malnutrition with a validated nutrition screening tools since study noted high prevalence of malnutrition and its association with pressure injuries.</p>	<p>associated with malnutrition</p> <ul style="list-style-type: none"> • Majority of patients were elderly in rehabilitation setting, only 39.5% had a high risk of pressure injuriesMUS • Limited cohort size 	
<p>Roberts, Chaboyer, & Desbrow, 2014 (Journal of Human Nutrition and Dietetics)</p>	<p>Cross sectional observational survey investigating nutrition-related practice in people with or at risk of PU</p>	<p>Participants were observed in 2 hospitals (4 wards) in Australia that had PU prevention programs (n=241)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Aged ≥ 18 years • Restricted mobility increasing risk of PU • Length of stay ≥ 3 days <p>Participant characteristics:</p> <ul style="list-style-type: none"> • Mean age 70 years • 59% male • 19.6% had infection, 17.1% respiratory condition, 53% hypertension, 33% chronic obstructive pulmonary disease, 32% diabetes, 26^ chronic renal failure • Mean length of stay 5 days 	<p>Practice was observed in each of the 4 wards for a random 7-day period in the 9 week data collection period</p>	<ul style="list-style-type: none"> • Semi-structured observational tool developed by academics and clinicians • Four researchers collected data • Pilot data testing on 10 participants used to test inter-rater and intra-rater reliability (both > 95%) • Participant patients observed for 24 hours including meal behavior and intake, questions on nutrition-related symptoms, weight • Chart audit 	<p>Documentation</p> <ul style="list-style-type: none"> • 71% had a documented weight and 34% had documented height • 59% had screening with malnutrition screening tool (MST) <p>Dietitian referrals</p> <ul style="list-style-type: none"> • 18% of those who had no MST did have a dietitian referral • 28.6% had a dietitian referral • 88.4% of people referred were reviewed by a dietitian • MV analysis showed predictors of dietitian referral were length of stay (OR 1.1, 95% CI 1 to 1.1, p<0.001) and being underweight (OR 4.0, 95% 1.9 to 8.4, p<0.001) <p>After dietitian referral</p> <ul style="list-style-type: none"> • 83.6% of people reviewed were prescribed nutritional support • Of these, 51.7% received and consumer nutritional supplement 	<ul style="list-style-type: none"> • No measure of impact of nutrition practices on preventing or healing PU • Small sample size 	<p>Indirect evidence: PU not an outcome measure</p>

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					Author conclusions: Nutrition-related behaviors need improving in acute care hospitals		
Ek, Unosson, Larsson, Von Schenck, & Bjurulf, 1991	RCT investigating effectiveness of nutritional outcomes as risk factors for pressure injuries , plus whether oral nutritional supplement on preventing and treating pressure injuries	<p>Participants were recruited consecutively in long-term care hospital in Sweden (n=495 included, 482 analyzed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Hospitalized for more than 3 weeks <p>Exclusion criteria:</p> <ul style="list-style-type: none"> None reported <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 80 years 14.1% had a pressure injury at baseline <u>28.5% of participants were malnourished</u> at start (defined as low values in 50% of following parameters: weight index, triceps skinfold, arm muscle circumference, pre-albumin, albumin, delayed hypersensitivity skin test) Malnourished participants had higher pressure injury rate at baseline (34.8% vs 20.6%, p<0.01) 	<p>Participants were randomized to receive either:</p> <ul style="list-style-type: none"> Standard supplement of total <u>400 kcal/day (16 En% protein, 36 En% fat, 48 En% carbohydrate)</u>, plus usual hospital diet (2,200 kcal/day), (n=not stated) Participants received the supplement orally twice daily (daily intake of 400kcal) , or Usual hospital diet only, 2,200 kcal/day, (n=not stated) Nutritional intervention was for up to 26 weeks 	<ul style="list-style-type: none"> Pressure injury incidence was evaluated on a weekly basis and described as persistent discoloration, epithelial damage, full skin thickness with or without cavity Size and status of pressure injuries assessed Percent pressure injuries healed Proportion of food eaten Modified Norton scale 	<p>Multivariable analysis for dietary items for predicting pressure injuries</p> <ul style="list-style-type: none"> Albumin being <36g/L 84% sensitivity, 31% specificity Food intake insufficient 41% sensitivity, 83% specificity 	<ul style="list-style-type: none"> No intention to treat analysis (19 participants with missing data excluded) Randomization, allocation concealment and blinding not reported Long intervention time may give more opportunity for the nutritional intervention to have an impact 	<p>Level of evidence: 1</p> <p>Quality: Low</p>
Kennerly et al., 2015	Observational analysis explore the use	Secondary data analysis from another study. Participants from nursing homes in the US	Participants were stratified by pressure injury risk to	<ul style="list-style-type: none"> Braden Nutritional Risk subscale screening 	Nutrition outcomes for people at moderate and high risk of pressure injuries	<ul style="list-style-type: none"> No formal evaluation of reliability or validity 	<p>Level of evidence: 4</p>

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	of Braden Scale Nutrition Subscale to evaluate severity of nutritional risk status	<p>had been recruited to a positioning intervention study (n=690 in sub-analysis)</p> <p>Inclusion in original study and this sub-analysis: Aged 65 years or more No pressure injury on admission</p> <p>Exclusion from sub analysis:</p> <ul style="list-style-type: none"> • Asian • Short stay patients • tube feeding • Missing Braden Scale data <p>Participant characteristics: Participants had Braden Scale Pressure Ulcer Risk Score of moderate (n=462) and high risk (n=228) Mean age range from 80.9 to 87.5 years Predominately white females</p>	participation in the repositioning study Braden scale used to evaluate pressure injury risk	<ul style="list-style-type: none"> • Dietary intake measured as mean % meal intake, meal timing, mean number of protein servings, protein sources, % intake of supplements and snacks • Weight outcomes • New pressure injury incidence 	<ul style="list-style-type: none"> • 61.9% people at moderate risk and 59.2% people at high risk ate mean 75% or more of their meal • Fewer than 18% overall ate less than 50% of meals <p>Mean Braden Scale Pressure Ulcer Risk Scale Nutrition Subscale performance</p> <ul style="list-style-type: none"> • Mean Braden Scale Pressure Ulcer Risk Scale score correlated with assessment on the Nutrition Subscale (p<0.001) • Mean Braden Scale Pressure Ulcer Risk Scale Nutrition Subscale was related to the mean meal intake • Diagnosis of nutritional disorder was more common in participants assessed as category 1 on nutritional subscale (4%) <p>Conclusions: Braden Nutrition subscale estimates dietary intake and for people at moderate or high risk of pressure injury and could be used as a nutritional screening tool, There was no formal evaluation of the reliability and validity of the tool for this purpose</p>	<ul style="list-style-type: none"> • No comparison to known reliable and valid nutrition screening tools 	Quality: moderate
Verbrugghe et al., 2013	Analytical cross-sectional prognostic study investigating prognostic factors for malnutrition in nursing homes	<p>n= 1,188 residents representing a random sample of older adults in 23 nursing homes in Belgium</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Birthday on an odd date • ≥55 yrs of age • Completed surveys <p>Characteristics:</p> <ul style="list-style-type: none"> • Mean age 84.3±7.7 yrs 	Assessments on all residents conducted by nursing staff	Dependent variable malnutrition as assessed on MNA	<ul style="list-style-type: none"> • 19.4% were malnourished and 38.7% were at risk for malnutrition • Presence of PU, recent hospitalization (< 3 months ago), being involved in a tailored nutritional intervention and lower cognitive state were significantly associated with malnutrition • Multivariate logistic regression with MNA <17 (malnourished) as dependent variable showed presence of PU was a potential predictor of malnutrition (OR=5.02, 95% CI 1.69 to 14.92, p<0.01) 	<ul style="list-style-type: none"> • Cross-sectional rather than longitudinal design • Poor sampling, unclear if sample is representative of population • Only those who completed full assessments included • Does not state how PU was assessed 	<p>Level of evidence: 4</p> <p>Quality: low</p>

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> Primarily females >50% fully dependent for dressing/washing 19.7% diabetes mellitus, 19.9% cardiovascular disease, 75.6% cognitive impairment 4.5% had a PU 	<p>Food intake, swallowing, energy assessment Minimal Eating Observation Form version II (MEOF)</p> <p>Functional and mental status MMSE, Katz Scale</p>		<ul style="list-style-type: none"> Conclusions: presence of PU was one of the major factors independently associated with malnutrition in older nursing home residents 	<ul style="list-style-type: none"> Cannot determine whether PU preceded malnutrition or duration of PU Unclear if PU prevalence similar between facilities 	
Allen, 2013	Quasi experimental design investigating the effect of a comprehensive multidisciplinary nutritional protocol and care planning on PU healing in adults over 60 years	<p>Participants were recruited from an acute long term care USA hospital, retrospective control group from record analysis (n=100)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> Aged ≥60 yrs Stage II or II PU <p>Exclusion:</p> <ul style="list-style-type: none"> Medical conditions prohibiting vitamin, zinc or iron intake <p>Characteristics:</p> <ul style="list-style-type: none"> 28% had stage II PUs and 72% had stage III PUs, primarily sacrum and coccyx Mean age 79.42±9 yrs Mean BWAT 32±8.1 (range 16 to 52, p=ns between groups) No co-morbidity reported 	<ul style="list-style-type: none"> Control group received standard care (diet according to physician orders) and were matched for experiment group participants on age, gender, PU stage, Braden scale (all data collected from record analysis, n=50) Experimental group (n=50) received a comprehensive nutritional protocol that included: <ul style="list-style-type: none"> Admission and weekly albumin/pre-albumin levels to determine level of nutritional support OT, dietitian, speech therapist review Protein supplement for all people with pressure injuries and increased protein supplementation for malnutrition Vitamin A, Z, zinc, iron supplementation 	<ul style="list-style-type: none"> PU risk assessed using Braden scale PU wound healing using Bates-Jensen Wound Assessment Tool with a PU considered to be resolved when 100% granulation tissue and at least 75% reduction in size. 	<ul style="list-style-type: none"> There was a significant difference between groups in tissue health by week 2 (38% versus 2%, p<0.005) and in week 3 (37% versus 23.4%, p<0.05) but no significant differences in weeks 4 and 5 <p>Conclusions: a multidisciplinary nutritional planned intervention that includes protein and vitamin/mineral supplementation may contribute to increased pressure injury healing (assessed as % tissue regeneration) in older adults</p>	<ul style="list-style-type: none"> No co-morbidities that may influence nutrition or healing are reported Drop outs were not considered in the analysis and were not equivalent between groups Relied on chart reviews for control group No blinding of assessor and used a subjective Likert-scale wound assessment tool 	<p>Level of evidence: 2</p> <p>Quality: low</p>

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			Experimental group received intervention until discharge or PU had a 75% reduction in size.				
Meijers et al., 2008	Cross-sectional study investigating whether a facility-wide nutritional guideline improved assessment and management of patients with pressure injuries	n=363 organizations in Netherlands, Germany and UK (from 1,087 invited to participate) Each facility delegated one person to respond to survey Characteristics: <ul style="list-style-type: none"> • 46.9% hospital-setting • 25.8% nursing home 21.6% home care • n=240 (66%) had a nutritional guideline • 58.8% respondents were nurses, 17.8% were dietitians, 85% were on a PU committee 	Investigation into differences in daily practice regarding nutritional care in patients with PU and possible barriers in providing patients nutritional support Data collected via standardized questionnaire	Daily practice regarding nutritional care in patients with PU and possible barriers in providing patients nutritional support	<ul style="list-style-type: none"> • Facilities with a guideline were more likely (p<0.05) than those without to: <ul style="list-style-type: none"> ○ always conduct nutritional screening for a patient with PU ○ conduct nutritional assessment at regular intervals ○ record weight gain , development of PU and improvement in PU healing as outcomes for success or failure of a nutritional intervention ○ Use BMI, clinical judgement or nutritional screening tools in conducting a nutritional assessment • There was no significant difference in the types of nutritional interventions used in facilities with or without a nutritional guideline • Facilities with a guideline were less likely (p=0.001) to have no barriers to care. • Knowledge and skills was the most important (p<0.006) care barrier in facilities with and without guidelines • Facilities without guideline other significant factors were no specific guidance (p=0.001), reimbursement restrictions (p=0.001) • In facilities with guidelines, barriers were lack of resources (p=0.001). <p>Conclusions: Having a nutritional guideline contributes to conducting of nutritional screening on a regular basis in daily practice</p>	<ul style="list-style-type: none"> • Unclear if responding facilities were reflective of overall facilities invited • Reported (not observed) practice, may have been biased by survey respondents perception, interest in PU and exposure to daily care within the facility • No independent analysis based on duration of guideline use in facility 	Level of evidence: 4 Quality: moderate

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					and reduces barriers to providing nutritional support		
Wojcik, Atkins, & Mager, 2011	Observational prognostic study relationship of diet and anthropometrics to wound severity	<p>Participants recruited from home living support programs in USA (n=31)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> >18 yrs Home care/supported living <p>Exclusion:</p> <ul style="list-style-type: none"> Ulcer of non-pressure aetiology Upper body contracture, chronic organ failure <p>Characteristics:</p> <ul style="list-style-type: none"> Age range 45 to 9 yrs Mean BMI in pressure injury participants was 25.9±12.45 Mean Braden score in pressure injury participants was 17.48±3.70 71% had pressure injury and 29% had venous stasis ulcer 42% overweight or obese, 39% underweight 45% type II diabetes and/or hypertension 	<ul style="list-style-type: none"> Food intake was assessed using a 3-day food intake record Anthropometric measurements were obtained using standard methodologies Braden Pressure Ulcer Risk Assessment tool was used to determine PU risk (≤16 any risk, ≤12 high risk) Wound severity determined as per the NPUAP guidelines 	<ul style="list-style-type: none"> Dietary intake Wound severity 	<p>Wound severity</p> <ul style="list-style-type: none"> 36% participants with pressure injury had high pressure injury severity (stage III or IV) 54.5% had no risk of pressure injury on BPURA Mean duration of pressure injury was 6.6±3.9 months <p>Diet and anthropometrics</p> <ul style="list-style-type: none"> 18% of participants supplemented diet with vitamins/minerals, liquid nutrients or both Estimated average requirement was met for all nutrients except fibre, magnesium, potassium and vitamins D, E and K. Energy, protein and zinc did not meet the estimated requirements in 41%, 32% and 54.5% of clients In multivariate analysis increasing wound severity was associated with lower intakes of vitamin A, vitamin K, magnesium and protein (p < 0.05) Higher Braden Scores were associated with higher protein intakes (p < 0.05) <p>Conclusions: community-living people with pressure injuries may be at risk for nutritional deficits due to unsatisfactory dietary intake and this may delay wound healing</p>	<ul style="list-style-type: none"> Small sample size may be biased due to case manager identifying for inclusion Data collection relied on honest recall of food intake over only 3 days Wide age range may bias findings Unclear if nutritional deficit increase risk of PU or PU increases risk of nutritional deficit 	Indirect evidence (included wounds of different etiology)

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Clinical questions 2,3 and 4: Nutritional interventions for preventing pressure injuries– individualized oral nutritional supplement (ONS)							
Amano et al., 2013	Retrospective cohort study reporting outcomes for people in palliative care at risk of pressure injuries treated with individualized nutritional supplement	<p>Participants were included from a retrospective review of records from a palliative care cancer unit in Japan (n=117 screened, n= 63 eligible)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> No cognitive impairment Performance status of ≤ 3 Palliative prognostic index (PPI) of ≤ 6 <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Died from unexpected causes <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 69 years Mean period of observation 22-28 days Mean PPI 3.5 	<ul style="list-style-type: none"> The comparative groups were: Those receiving an individualized <u>nutritional support to meet or exceed energy needs</u> calculated using Harris-Benedict equation plus protein 1.0-1.2g/kg body weight. Intervention included exploring and adjusting causes of malnutrition, encouraging feeding, offering snacks and supplements, total parenteral nutrition or peripheral nutrition (n=22) Not receiving any individual nutrition support (n=41) 	<ul style="list-style-type: none"> Pressure injuries present in the last 48 hours of life Pressure injuries categorized on NPUAP scale 	<p>Pressure injuries \geq stage 1</p> <p>Significantly fewer of intervention group had a pressure injury present in last 48 hours of life (14% versus 46%, p=0.012)</p>	<ul style="list-style-type: none"> Non-randomized Range of interventions used to meet nutritional requirements makes it unclear if any specifically were effective Unclear if individuals had PIs on admission/when observation commenced Retrospective design relied on documentation 	<p>Level of evidence: 3</p> <p>Quality: low</p>
Roberts, Chaboyer, Leveritt, Banks, & Desbrow, 2014	Observational study describing the energy and protein intakes of hospitalized people at risk for pressure injuries and to identify predictors of eating inadequately	<p>Participants were recruited in four wards at two hospitals in Australia (n=241 recruited, n=184 with complete data)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Adult patients with restricted mobility 	No intervention	<ul style="list-style-type: none"> All participants were observed for 24 hours Information on oral intake and observed nutritional practices was collected. A chart audit gathered other demographic characteristics, clinical, anthropometric, and dietary information. T-tests or one-way analysis of variances were used to identify differences in total energy and protein 	<p>Energy and protein intake</p> <ul style="list-style-type: none"> Mean energy of participants was 5917\pm2956 kJ Mean protein intakes of participants was 54\pm28 g In an analysis of estimated energy and protein requirements (n=93 participants), only 45% (n = 42) and 53% (n =49) met \geq75% of estimated energy and protein requirements, respectively. <p>Multivariate analysis</p>	<ul style="list-style-type: none"> Small sample size, unclear if diet at different hospital locations influenced findings There was evidence for ONS as a predictor of eating adequately. Other factors previously shown to influence nutritional intake should also 	<p>Indirect evidence (PU not an outcome measure)</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
				intakes. Univariate and multivariate regression analyses were conducted to determine predictors of eating inadequately (i.e., intake of <75% of estimated energy and protein requirements).	<ul style="list-style-type: none"> Participants in the renal ward were 4.1 and 4.6 times more likely to be eating inadequately for energy and protein, respectively (p=0.05). Patients who consumed any amount of oral nutrition support were 5.1 and 15.5 times more likely to have adequate intake of energy and protein, respectively (p<0.05). <p>Author conclusions: Renal patients are more likely to be eating inadequately, although any consumption of oral nutrition supplement (ONS) seems to increase likelihood of achieving adequate nutritional intake.</p>	be considered, as well as potential high-risk groups (e.g. renal patients).	
Ek et al., 1991	RCT investigating effectiveness of oral nutritional supplement on preventing and treating pressure injuries	<p>Participants were recruited consecutively in long-term care hospital in Sweden (n=495 included, 482 analyzed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Hospitalized for more than 3 weeks <p>Exclusion criteria:</p> <ul style="list-style-type: none"> None reported <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 80 years 14.1% had a pressure injury at baseline 	<p>Participants were randomized to receive either:</p> <ul style="list-style-type: none"> Standard supplement of total 400 kcal/day (16 En% protein, 36 En% fat, 48 En% carbohydrate), plus usual hospital diet (2,200 kcal/day), (n=not stated) Participants received the supplement orally twice daily (daily intake of 400kcal) , or Usual hospital diet only, 2,200 kcal/day, (n=not stated) Nutritional intervention was for up to 26 weeks 	<ul style="list-style-type: none"> Pressure injury incidence was evaluated on a weekly basis and described as persistent discoloration, epithelial damage, full skin thickness with or without cavity Size and status of pressure injuries assessed Percent pressure injuries healed Proportion of food eaten Modified Norton scale 	<p>Pressure injury incidence in people without a pressure injury at baseline</p> <p>Rate of pressure injuries was lower in the group receiving supplements (9.9% vs. 12%, p = reported as not significant)</p> <p>Participants developing pressure injuries had lower functional levels for activity, mobility, food intake, continence and overall physical condition (p<0.01)</p> <p>Multivariable analysis for dietary items for predicting pressure injuries</p> <ul style="list-style-type: none"> Albumin being <36g/L 84% sensitivity, 31% specificity 	<ul style="list-style-type: none"> No intention to treat analysis (19 participants with missing data excluded) Randomization, allocation concealment and blinding not reported Long intervention time may give more opportunity for the nutritional intervention to have an impact 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> 28.5% of participants were <u>malnourished</u> at start (defined as low values in 50% of following parameters: weight index, triceps skinfold, arm muscle circumference, pre-albumin, albumin, delayed hypersensitivity skin test) Malnourished participants had higher pressure injury rate at baseline (34.8% vs 20.6%, $p < 0.01$) 			<ul style="list-style-type: none"> Food intake insufficient 41% sensitivity, 83% specificity 		
I. Bourdel-Marchasson et al., 2000	RCT exploring the effect of oral nutritional supplement on pressure injury incidence	<p>Participants were recruited in hospital wards in France where >40% of inpatients were older than 65 years (n=672)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Aged older than 65 years In the acute phase of a critical illness Unable to move or to eat by themselves at admission <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Patients with pressure injuries at admission <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 83 years Participants assigned to ONS group presented with lower dependence in ADL, higher risk of developing 	<p>Participants were randomized (stratified by medical specialty) to receive either:</p> <ul style="list-style-type: none"> Standard diet of 1,800 kcal/day plus two <u>oral supplements of 200 kcal each (with 30% protein, 20% fat, and 50% carbohydrate in addition to minerals and vitamins such as zinc and vitamin C (n=295), or</u> Control/comparison of a standard diet of 1800 kcal/day (n=377) 	<ul style="list-style-type: none"> Occurrence of pressure injuries recorded each day by the nurse on duty and assigned to of one of four grades defined by the Agency for Health Care Policy and Research Follow up period: 15 days or until death or discharge 	<p>Nutritional intake</p> <p>The intervention group had significantly higher energy ($p=0.006$) and protein ($p < 0.001$) intakes in the intervention group.</p> <p>Pressure injury incidence</p> <ul style="list-style-type: none"> There was no significant difference between groups for pressure injury incidence (40.6% intervention group versus 47.2% in control group) 90% of pressure injuries experienced in the trial were Category/Stage I pressure injuries <p>Adverse events</p> <p>Death did not differ between the two groups</p> <p>Author conclusions: Protein-calorie supplementation in</p>	<ul style="list-style-type: none"> Individual randomization was not performed Non-blinded nutritional approaches in the same ward Compliance in the first week was moderate (60% of ONS prescribed – probably due to loss of appetite during critical illness) and good during the second week. Despite difference in baseline features, the same difference have been accounted for in the analysis. 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<p>pressure injuries, and lower albumin levels</p> <ul style="list-style-type: none"> Participants not assigned to ONS were at higher risk of developing pressure injuries: hazard ratio (HR)= 1.57 (95% confidence interval (CI) 1.03 to 2.38), p=0.04) 			critically ill older adults resulted in higher energy and protein intakes and lower risk of developing PUs, but did not significantly influence the incidence of pressure injuries experienced		
Houwing et al., 2003	RCT exploring the effect of a nutritional supplement on preventing pressure injuries	<p>Participants were recruited in three centers in the Netherlands (n=103)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Hip fracture <p>Exclusion criteria:</p> <ul style="list-style-type: none"> terminal care metastatic hip fracture insulin-dependent diabetes renal disease (creatinine >176mmol/l) hepatic disease morbid obesity [BMI >40] pregnancy or lactation <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 80- 82 years, Mean baseline BMI 23.7 to 24.2 kg/m² <p>Mean pressure ulcer risk score 11</p> <p>Indicates <u>participants were malnourished</u></p>	<ul style="list-style-type: none"> All participants underwent surgery for hip fracture Participants were randomized to receive either: <ul style="list-style-type: none"> Disease-specific high protein supplement (500 kcal/day, 32 En% protein + 6 mg arginine, 20 mg zinc, 500 mg Vitamin C, 200 mg Vitamin E, 4 mg carotenoids). (n =51), or Placebo (non-caloric water based drink (n =52) Intervention was delivered orally as 400ml daily between meals for 4 weeks or until discharge 	<ul style="list-style-type: none"> Incidence of pressure injuries Days to onset of pressure injury Total wound size Category/Stage of pressure injury using EPUAP system Duration of pressure injury 	<p>Incidence of pressure ulcers</p> <ul style="list-style-type: none"> There was no significant difference in incidence of pressure injuries between intervention and control groups (52.9% vs 57.6%, p=0.42) Intervention group had significantly fewer Category/Stage II pressure injuries (9% difference, 95% confidence interval 7% to 25%, p=0.345) There was a trend towards slower onset of pressure injuries in the intervention group (3.6±0.9 days vs 1.6±0.9 days, p=0.09) <p>Conclusions: Nutrition support may delay onset of pressure injuries in people at high risk following hip fracture surgery</p>	<ul style="list-style-type: none"> Double blind study Power calculation required 35 patients to detect 25% difference in pressure injury incidence Methods of randomization, allocation concealment and blinding are not reported Small study 	<p>Level of evidence: 1</p> <p>Quality: High</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence: Quality: Low
Delmi et al., 1990	RCT investigating clinical benefits of a high protein nutritional supplement	<p>Participants were consecutive older people with fractured femur recruited in a hospital in Switzerland and transferred to a recovery hospital (n=59)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Aged over 60 years • Admitted in 2 week study period with a neck of femur fracture due to accidental fall <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Fracture due to other causes • Dementia • Renal, hepatic, endocrine disease, some gastric disorders and some medications <p>Participant characteristics:</p> <ul style="list-style-type: none"> • All <u>participants were at risk of malnutrition</u> (below normal Vit A, carotene, retinol binding protein) • Mean baseline serum albumin 36.3 to 37.1 g/L • Mean age 80 to 83 years • Experimental group had higher 25 OHD Vitamin D status (26 nmol/L vs. 13 nmol/L) 	<p>Participants were in a surgical ward following neck of femur surgery, some were transferred to a recovery hospital</p> <p>Participants were randomized to receive:</p> <ul style="list-style-type: none"> • <u>High protein oral supplement</u> (254 kcal/day, 32En% protein, 21En% fat, 46En% carbohydrate + 525 mg Ca, 750 IU Vitamin A, 25 IU Vitamins D, vitamins E, C and B). Total 254kcal/day administered once daily (n =27, 9 discharged), or • Standard hospital diet (n=32, n=15 discharged) • Nutritional intervention administered for up to 32 days 	<ul style="list-style-type: none"> • Pressure ulcer incidence • Blood biochemistry (albumin) • length of hospital stay, mortality and complications • dietary intake • transferrin, liver enzymes, • percent participants with favorable clinical outcome (unclear how this was measured) • Follow up at 6 months 	<p>Pressure injury incidence during hospital stay</p> <ul style="list-style-type: none"> • Incidence of pressure injuries was lower in surgical hospital in the supplement group (7.4% vs 9.3%, p=not reported) • Incidence of pressure injuries was lower in recovery hospital in the supplement group (0% vs 33.33%, p=not reported) <p>Pressure injury incidence at 6 months</p> <ul style="list-style-type: none"> • Incidence of pressure injuries at 6 months was lower in people receiving supplements (0% vs 7.4%, p=not reported) <p>Other clinical outcomes</p> <ul style="list-style-type: none"> • Individuals in high protein supplement had higher intake of energy (mean 23% more) and protein (mean 62% more) • Oral meal intake was similar between groups • “Favorable course” was higher in individuals with supplementation during recovery phase (p<0.05) and at 6 months (p<0.02) <p>Cost-related outcomes</p> <p>Significantly shorter hospital stay for the group receiving high protein supplement (24 days vs 40 days)</p> <p>Adverse events</p> <p>No significant difference in rate of complications anaemia, cardiac failure, infection, gastrointestinal ulcers.</p>	<ul style="list-style-type: none"> • Randomization, allocation concealment not reported • Appears to be not blinded • Baseline pressure injuries not reported • Method of assessing pressure injuries, and Category/Stage not reported • Method of evaluating overall outcome is not reported and appears to be non-blinded • Pressure injury prevention strategies not reported 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Horn et al., 2004	Retrospective cohort study to identify factors associated with pressure injuries	<p>Participants were recruited in 95 longer term care facilities in the US (n=1524)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Aged 18 years or older • Length of stay 14 days or longer • No existing pressure injury • Braden Scale score of 17 or less indicating pressure injury risk <p>Exclusion criteria: No additional criteria</p>	<ul style="list-style-type: none"> • Some residents received a non-defined disease specific enteral formula (n=44) • Some residents received a high calorie/high protein enteral formula (n=169) • Some residents received a standard oral medical nutritional supplement (n=134) 	<ul style="list-style-type: none"> • Incidence of pressure injuries with record on tissue characteristics, depth, length and width, wound area, tunneling, undermining, infection signs and symptoms all recorded • Braden Scale score • Demographics • Concurrent medical conditions and severity • Staffing ratios in facility • Data was obtained from medical record reviews • Data was collected by multidisciplinary team of researchers • 12-week study period 	<p>Pressure injury incidence</p> <ul style="list-style-type: none"> • Facility acquired pressure injury incidence was 29% <p>Association between enteral disease specific formula and pressure injury incidence</p> <ul style="list-style-type: none"> • Receiving an enteral disease-specific formula was significantly associated with reduction in Category/Stage I to IV pressure injuries (OR=0.35, 95% CI 0.16 to 0.77, p=0.009) but the results were not significant were the analysis was limited to Category Stage II or greater pressure injuries (OR=0.38, 95% CI 0.17 to 0.86, p=0.19) <p>Association between enteral high calorie/high protein formula and pressure injury incidence</p> <ul style="list-style-type: none"> • Receiving high calorie/high protein formula was associated with decreased likelihood of a Category/Stage I pressure injury (OR = 0.48, 95% CI 0.32 to 0.72, p <0.001) and results remained significant when limited to Category Stage II or greater pressure injuries (OR=0.45, 95% CI 0.29 to 0.70, p<0.01) <p>Association between oral nutritional supplements</p>	<ul style="list-style-type: none"> • Retrospective study relying on data base records • No description of the specific ingredients in formulas and supplements and regimen is not reported • Logistic regression is not reported for individual patient characteristics 	<p>Level of evidence: 3</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					<ul style="list-style-type: none"> Receiving oral nutritional supplements was associated with decreased likelihood of a Category/Stage I pressure injury (OR = 0.57, 95% CI 0.36 to 0.90, p <0.016) and results remained significant when limited to Category Stage II or greater pressure injuries (OR=0.43, 95% CI 0.25 to 0.72, p<0.001) 		
Hartgrink, Wille, Konig, Hermans, & Breslau, 1998	RCT investigating effect of an oral nutritional formula via nasogastric tube on prevention of pressure injuries	<p>Participants were recruited in a hospital in Netherlands (n=149 randomized, 129 participated in trial, 101 remained in study at week 2)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Hip fracture Pressure injury risk score ≥8 points <p>Exclusion criteria:</p> <p>Category/Stage II or greater pressure injury</p> <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 83-84 years baseline serum albumin 39 g/L total protein 68-69.6 g/L Pressure injury risk score indicated that all participants were at high risk of pressure injury 15.5% had a Category/Stage I pressure injury at baseline 	<ul style="list-style-type: none"> All participants had a standard hospital mattress All participants had hip fracture surgery Participants were randomized to receive either: <ul style="list-style-type: none"> Formula (1,500 kcal/day, 16.6% protein plus standard hospital diet, commenced within 24 hours of surgery and administered as 1L/day via nasogastric tube) (n=48) Standard hospital diet (n=53) Intervention delivered for 2 weeks 	<ul style="list-style-type: none"> Pressure injury incidence a Category/Stage of pressure injury Pressure injury risk score Blood biochemistry (total protein, albumin, hemoglobin) Dietary intake 	<p>Pressure injury incidence (ITT analysis)</p> <p>Pressure injury (any Category/Stage) incidence was not significantly difference between the two groups at 2 weeks (52% tube supplemented group versus 69% standard diet only, p=0.69) Per protocol analysis also showed no significant difference in Category/Stage pressure injuries between the two groups</p> <p>Other outcome measures</p> <ul style="list-style-type: none"> Supplement group had significantly higher energy and protein intake (p<0.001) No difference in pressure injury risk score or blood biochemistry at 2 weeks 	<ul style="list-style-type: none"> Recruitment of participants is poorly reported Methods of randomization, allocation concealment and blinding are not reported Power calculated for sample size of 60 Two physicians reached agreement on Category/Stage of pressure injuries 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical questions 5,6 and 7: Nutritional interventional for <u>treating</u> pressure injuries – high energy oral nutritional supplement (ONS)							
<p>Ohura et al., 2013</p> <p>Note, this study is likely a repeat publication (in Japanese) of Ohura et al 2011.</p>	<p>RCT exploring the effects of nutrition intervention for pressure injury</p>	<p>Participants were recruited from 35 long-term care facilities in Japan (n=59)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Patients with pressure injury (Stage III-IV) on either sacrum, coccyx, greater trochanter, or heels, <u>Malnutrition and tube feeding</u> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Pocket larger than 2 cm, dry or yellowish necrotic tissue over >20%. <p>Participant characteristics :</p> <ul style="list-style-type: none"> Average 80.6±8.8 years for intervention group and 80.1±7.7 years for control group 	<ul style="list-style-type: none"> Participants were randomized to receive either: <ul style="list-style-type: none"> Basal Energy Expenditure (BEE) x1.1(activity factor) x1.3-1.5(stress factor) (n=29), or BEE x1.1 x1.1 x1.3 (control, n=21) Energy levels administered <ul style="list-style-type: none"> 37.9±6.5 kcal/kg/day for intervention group 29.1±4.9 kcal/kg/day for control group 	<ul style="list-style-type: none"> The size of pressure injury (cm²) measured every 2 weeks nutritional states measured every 6 weeks), adverse events were measured for 12 weeks 	<p>Healing of pressure injury</p> <ul style="list-style-type: none"> Healing rates were not significantly different between intervention and control groups (24% vs 19%) People receiving intervention had faster healing (p<0.001) <p>Nutritional outcomes</p> <p>Weight, waist circumference (p<0.001), suprailiac skinfold thickness (p<0.01), thigh circumference, prealbumin (p<0.05) were significantly different between intervention group and control group.</p> <p>Adverse events</p> <p>The incidence of adverse events was not significantly different between groups (p=0.360).</p> <p>Author conclusions: Nutrition intervention improve the nutrition states and also accelerated the healing of pressure injury.</p>	<ul style="list-style-type: none"> Not blinded, methods not reported in detail As nutrition intervention include more protein than the amount the guideline recommended, it is not sure whether the effect is due to the increase of energy or protein. The level of nursing might vary among the facilities. Pressure injuries with pocket or necrotic tissues are not included. 	<p>Level of evidence: 1</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
S. Iizaka, Kaitani, Nakagami, Sugama, & Sanada, 2014	Cohort study evaluating clinical validity of estimated energy requirement (30kcal/kg) and the average protein requirement (0.95g/kg) in older hospitalized people with pressure injuries by assessing nutritional status and wound healing.	<p>Secondary analysis of data from a clinical trial conducted in 29 institutions (n= 194)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> aged ≥65 years pressure injuries <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 80.7±7.5 20% diabetes mellitus 63.4% had deep pressure injuries and 36.6% had superficial pressure injuries Mean DESIGN-R score 15.2±9.8 	<ul style="list-style-type: none"> Participants were involved in an RCT that related to wound diagnosis and management Participants in both groups in the RCT had equivalent nutritional management Energy and protein intake were determined from medical records on a typical day and dichotomized by meeting the estimated average requirement. 	<ul style="list-style-type: none"> Nutritional status evaluated by weight, body mass index (BMI), anthropometric measurements and biochemical tests. Serum levels of albumin, C-reactive protein, blood urea nitrogen (BUN) and creatinine, estimated glomerular filtration rate (eGFR) measured using hospitals' standard procedures Nutritional intake was evaluated based on nursing records and analyzed as a continuous or a categorical variable. The cut-off points were set at 30 kcal/kg for energy and 0.95 g/kg for protein Pressure injury location, wound severity (according to the DESIGN-R tool) evaluated by WOCN nurses Outcomes evaluated over 3 weeks 	<p>Wound healing assessed on DESIGN-R tool</p> <ul style="list-style-type: none"> Energy and protein intake were associated with wound healing for deep pressure injuries (p=0.013 for both) Energy and protein intake were associated with improvement in exudate and necrotic tissue Energy and protein intake were not associated with any significant change in superficial pressure injuries. <p>Weight and anthropometric changes</p> <ul style="list-style-type: none"> Meeting the energy requirement was associated with changes in weight (p<0.001), arm muscle circumference (p=0.003) and serum albumin level (p=0.016). Meeting the protein requirement was associated with changes in weight (p<.001) and serum albumin level (p=0.043). These markers decreased in participants who did not meet the requirement, but were stable or increased in those who did meet protein requirements. 	<ul style="list-style-type: none"> Relatively short follow-up period that may not have been adequate to assess changes that take time to occur following nutrient intake Weight measurements were based on each hospital's manual and device and could have produced measurement errors. Nutritional intake evaluated based on medical records from a typical day at baseline. Data on proportion of dietary intake at each meal, and content/volume of supplements Data on energy and protein content of meal collected from menus. Large variability in nutrient intake observed. 	<p>Level of evidence: 3</p> <p>Quality: low</p>
Ek et al., 1991	RCT investigating effectiveness of oral nutritional supplement on preventing and treating	<p>Participants were recruited consecutively in long-term care hospital in Sweden (n=495 included, 482 analyzed)</p> <p>Inclusion criteria:</p>	<p>Participants were randomized to receive either:</p> <ul style="list-style-type: none"> Standard supplement of total 400 kcal/day (16 En% protein, 36 En% fat, 48 En% carbohydrate), plus usual hospital diet (2,200 kcal/day), (n=not stated) 	<ul style="list-style-type: none"> Pressure injury incidence was evaluated on a weekly basis and described as persistent discoloration, epithelial damage, full skin thickness with or without cavity 	<p>Percent pressure injuries healed</p> <ul style="list-style-type: none"> No significant difference in pressure injuries completely healed (supplement group 41.8% vs control group 30.3%) No significant difference in pressure injuries that improved 	<ul style="list-style-type: none"> No intention to treat analysis (19 participants with missing data excluded) Randomization, allocation 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	pressure injuries	<ul style="list-style-type: none"> Hospitalized for more than 3 weeks <p>Exclusion criteria:</p> <ul style="list-style-type: none"> None reported <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 80 years 14.1% had a pressure injury at baseline 28.5% of participants were <u>malnourished</u> at start (defined as low values in 50% of following parameters: weight index, triceps skinfold, arm muscle circumference, pre-albumin, albumin, delayed hypersensitivity skin test) Malnourished participants had higher pressure injury rate at baseline (34.8% vs 20.6%, $p < 0.01$) 	<p>Participants received the supplement orally twice daily (daily intake of 400kcal) , or</p> <ul style="list-style-type: none"> Usual hospital diet only, 2,200 kcal/day, (n=not stated) Nutritional intervention was for up to 26 weeks 	<ul style="list-style-type: none"> Size and status of pressure injuries assessed Percent pressure injuries healed Proportion of food eaten Modified Norton scale 	<p>(supplement group 51.3%, vs control group 43.9%)</p> <p>Multivariable analysis for dietary items for predicting pressure injuries</p> <ul style="list-style-type: none"> Albumin being $< 36\text{g/L}$ 84% sensitivity, 31% specificity Food intake insufficient 41% sensitivity, 83% specificity 	<p>concealment and blinding not reported</p> <ul style="list-style-type: none"> Long intervention time may give more opportunity for the nutritional intervention to have an impact 	
Breslow, Hallfrisch, Guy, Crawley, & Goldberg, 1993	Quasi experiment comparing standard enteral formula to a high protein formula for healing pressure injuries	<p>Participants were recruited in nursing homes in the US (n=28)</p> <p>Inclusion criteria: Pressure injury of Category/Stage II or greater</p> <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 72 years Baseline BMI and albumin were comparable and risk 	<p>Participants received either:</p> <ul style="list-style-type: none"> Standard high protein formula (763 kcal/day, 24% protein for oral participants and volume to meet individual requirements in tube fed; n=15) Regular protein formula (14% protein, n=13) 	<ul style="list-style-type: none"> Pressure ulcer incidence Pressure injury area Dietary intake Anthropometry (body weight, BMI) Blood biochemistry (total protein, albumin, transferrin, haemoglobin, haematocrit, zinc), mortality, complications (diarrhoea) 	<p>Pressure injury reduction in wound surface areas</p> <ul style="list-style-type: none"> People in the high protein group has a significant greater reduction in pressure injury surface area compared to baseline (mean area decrease – $4.2 \pm 7.1\text{cm}^2$, $p < 0.02$) People in the regular protein intake group had no significant change in pressure injury area Change in pressure injury area was correlated with dietary protein intake ($r = 0.50$, $-p < 0.01$) 	<ul style="list-style-type: none"> Pressure injury management not standardised Pressure injury prevention strategies e.g. support surfaces, were different between the groups (some on air-fluidised beds, some on alternating pressure air mattress overlay on standard mattress) 	<p>Level of evidence: 2</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<p>factors, age, gender, diagnoses were similar</p> <ul style="list-style-type: none"> • Mostly bedridden • Primarily incontinent • Category/Stage II pressure injuries (n = 9), III (n = 8) and IV (n = 16) 			<p>and with calorie intake per kg (r= -0.41, p<0.03)</p> <ul style="list-style-type: none"> • Decrease in surface area of Category/Stage IV pressure injuries was higher in the high protein group versus the standard protein group (p<0.05) <p>Other outcomes No significant changes in anthropometry or biochemistry</p>		
Emanuele Cereda, Gini, Pedrolli, & Vanotti, 2009	Single blinded RCT investigating disease-specific nutritional approach as a strategy to promote PU healing	<p>Participants were residents in 4 LTC facilities in Italy (n=28)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Aged ≥ 65 yrs • Stage II, III & IV PUs on NPUAP staging system <p>Exclusion:</p> <ul style="list-style-type: none"> • Acute illness • Chronic disease including diabetes mellitus, PVD • Lack of adherence to diet • Immunosuppressant <p>Characteristics:</p> <ul style="list-style-type: none"> • Primarily female, mean age approx. 82 years. • 64.3% were tube fed (p=ns between groups) • Control group had significantly more PUs of lesser severity (p=0.03) • No significant differences in BMI (20.8±3.2 treatment 	<ul style="list-style-type: none"> • All participants had similar general PU care. • All participants received 30 kcal/kg of body weight. • Participants were randomised to receive either: <ul style="list-style-type: none"> ○ Standard hospital diet with additional 400 mL oral supplement containing 500 kcal, 34 g protein, 6 g arginine, 500 mg vit C, 18 mg zinc OR if tube fed 1,000mL high protein formula (20% energy from protein enriched with arginine, zinc, vit C) infused with isocaloric formula to reach energy requirements (intervention group, n=15 but 2 deceased, analysis was n=13) ○ Standard hospital diets (16% energy from protein) OR standard enteral formula (control group, n=15) 	<p>Primary outcomes were: PU healing assessed using</p> <ul style="list-style-type: none"> • Pressure Ulcer Scale for Healing (PUSH; 0=complete healing and 17=greatest severity) and • Lesion area measurements (mm² and % healed) <p>12-week follow-up</p>	<p>Change in biochemical parameters over 12 weeks</p> <ul style="list-style-type: none"> • weight gain: mean 1.8±2.7 kg treatment, 0.7±2.6 kg control, p=ns • total protein changes: mean 3.3±7.0g/L treatment, 2.2±4.5g/L control, p=ns • Albumin, transferrin, lymphocytes and haemoglobin all p=ns between groups <p>PU healing over 12 weeks</p> <ul style="list-style-type: none"> • Both groups had significant improvement in PU healing (p<0.001 for both groups) • PUSH score became statistically significantly different between groups at Week 12 (-6.1 ±2.7 vs -3.3 ±2.4, p<0.05) • Pressure injury surface area was significant by week 8 (favoured treatment: -1,140.9 ± 669.2mm² vs -571.7 ±391.3mm², p<0.05) 	<ul style="list-style-type: none"> • Small sample size • absence of a control group supplemented only with protein • orally and tube-fed subjects were analyzed together • no intention-to-treat analysis was performed • Excluded any co-morbidities so results are not generalizable (from 371 potential participants, only 39 met inclusion criteria) • Control group had significantly less severe PUs at baseline • Superior healing only evident after 8 to 12 weeks of treatment 	<p>Level of evidence: 1</p> <p>Quality: moderate</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		group versus 23.1±5.0 control group)			Conclusions: Rate of PU healing in older adults appears to accelerate when a nutrition formula enriched with protein, arginine, zinc and vitamin C is administered for at least 8 weeks		
Ohura, Nakajo, Okada, Omura, & Adachi, 2011	RCT investigating effectiveness of nutritional intervention that uses calorie calculation according to Basal Energy Expenditure (BEE) in promoting pressure injury healing	<p>n=60 older Japanese patients</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Tube fed • Sacral, coccygeal, trochanter or calcaneal stage III or IV PUs of according to NPUAP classification • albumin of 2.5 to 3.5g/dL • Braden scale score of 9 to 17 <p>Exclusion:</p> <ul style="list-style-type: none"> • Liver or renal disease, severe diabetes mellitus, arteriosclerosis, malignancy • >20% necrotic tissue or 2cm depth of PU or multiple PUs <p>Characteristics:</p> <ul style="list-style-type: none"> • No significant differences between groups at baseline • Mean age approx. 81 years (range 58 to 95) • Mean BMI 18 	<p>All participants were managed according to local PU guidelines including pressure mattress and 2 hourly repositioning.</p> <p>Participants were randomised to either:</p> <ul style="list-style-type: none"> • Same number of calories as before participating in this trial (control group, n=29) • calories according to the range of Basal Energy Expenditure x active factor 1.1 x stress factor 1.3 to 1.5 (treatment group, n=21) <p>4-week protocol</p>	<ul style="list-style-type: none"> • Mean daily caloric intake • Changes over time in nutritional state • Changes over time in PUs using DESIGN-R scale • Risk for development of PU • Adverse events <p>Follow-up at 12 weeks</p>	<p>Energy intake</p> <ul style="list-style-type: none"> • Mean daily calories administered during the intervention period were 1,092.1 ± 161.8 kcal in the control group and 1,383.7 ± 165.6 kcal in intervention group • Mean daily calories based on weight were 29.1±4.9 kcal/kg/day in the control group and 37.9±6.5 kcal/kg/day <p>Anthropometric outcomes</p> <ul style="list-style-type: none"> • Statistically significant increases were noted for the intervention group over the control group for weight (p<0.001), waist circumference (p<0.001), supra-iliac skinfold thickness (p<0.005) and thigh circumference (p<0.005). <p>Pressure injury outcomes</p> <ul style="list-style-type: none"> • Pressure injuries healed within 12 weeks for four subjects in the control group and seven subjects in the intervention group. Interaction between groups was significant for mean ulcer size (p<0.001) • Pressure injuries depth measure on DESIGN-R decreased more steadily in intervention group (p<0.005) 	Small sample size	<p>Level of evidence: 1</p> <p>Quality: moderate</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					<ul style="list-style-type: none"> No significant changes over time for each parameter of the DESIGN scale <p>Pressure injury risk</p> <ul style="list-style-type: none"> No significant changes over time for each parameter of the Braden scale <p>Conclusions: a nutritional intervention calculated on Basal Energy Expenditure x active factor 1.1 x stress factor 1.3 to 1.5 may be related to increased PU healing in older adults being tube fed</p>		
Yamamoto et al., 2009	Cohort study reporting on relationship between total nutritional intake and healing of pressure injuries	<p>Participants were recruited from a Japanese medical centre in 2007 to 2008. n=40</p> <p>Exclusion:</p> <ul style="list-style-type: none"> Discharged home or death within one month of PU identification <p>Characteristics:</p> <ul style="list-style-type: none"> Primarily stage II sacral PUs No significant difference in height, weight BMI Improvement group mean age 67.4±16.4yrs (range 22 to 94) Unimproved group mean age 71.7±10.9yrs (range 51 to 92) 14/19 in unimproved group had malignancy versus 5/21 in improved group. 	<p>All participants had appropriate support surfaces and wound treatment.</p> <ul style="list-style-type: none"> Improvement group consisted of those participants whose PUs were assessed as having improved (n=21) Non-improvement group consisted of those participants whose PUs were assessed as not improving (n=19) 	<ul style="list-style-type: none"> PUs observed weekly commencing 1 month after PU identified. Size, depth, amount of granulation, exudate and necrotic tissue and infection were documented weekly. Participants were classified as “improved” or “unimproved” based on PU assessment. (methods of data collection not reported). Total energy intake measured on the day PU discovered, 2 weeks prior to PU and both 2 and 4 weeks after PU discovered. (method of assessment not reported). 	<ul style="list-style-type: none"> 38% of improved group and 26% unimproved group presented with Category/Stage I pressure injuries Mean total energy intake per kg body weight was higher in improvement group (always >30 kcal/kg) versus unimproved group (never >20 kcal/kg, p<0.001). Mean daily protein intake in the improvement group (always > 45g daily) higher than unimproved group (approx. 20 g daily, p<0.005) <p>Conclusions: there may be a correlation between energy intake and PU healing, however the confounding issues were not addressed in this particular study.</p>	<ul style="list-style-type: none"> Difference in PU severity at baseline Baseline comorbidity not considered in analysis. Unimproved group had a very high level of malignancy that likely influenced both energy intake ability and healing. Method of data collection for daily energy intake is not reported (e.g. food diary) Method of PU measurement is not reported (e.g. is size determined objectively) Patients who discharged or died were excluded 	<p>Level of evidence: 3</p> <p>Quality: low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Parenteral/enteral feeding for preventing and treating pressure injuries							
I. Bourdel-Marchasson, Dumas, Pinganaud, Emeriau, & Decamps, 1997	Retrospective cohort study exploring tolerance and improvement of tube feeding practices	<p>Participants were recruited respectively in a geriatric centre in France over 4 years (n=108)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Had a PEG insertion • Control group had swallowing difficulties <p>Exclusion criteria: Not reported</p> <p>Participant characteristics:</p> <ul style="list-style-type: none"> • Mean Kuntzmann's score of dependence was 9.6 • 65.5% in experimental group and 14.3% in control group had pressure injuries at baseline (p <0.001; Category/Stage not reported) • Included older adults plus younger people with neurological disorders 	<p>Standard formula for which composition was not reported (developed using recommended daily intake in France) delivered via percutaneous endoscopic gastrostomy using constant feeding of 120mL/hour(PEG, n = 58)</p> <p>Routine care consisting of usual diet (n=50)</p>	<ul style="list-style-type: none"> • Pressure ulcer incidence • Proportion of pressure injuries: healed, improved, unchanged, or worsened • Mortality and complications (vomiting, ileus, gastrooesophageal reflux, bronchorrhea/dyspnea, aspiration pneumonia) • Follow up was between 48–72 weeks 	<p>Pressure injury incidence There was no significant difference between groups for pressure injury incidence (10.3% in intervention vs. 16% in control)</p> <p>Pressure injury healing In the intervention group, 17.5% were healed and 32.5% improved during the study In the control group, 20% healed</p> <p>Adverse outcomes</p> <ul style="list-style-type: none"> • Mortality rates were not different between groups • 80% of the PEG group experienced a cutaneous complication around insertion site included abscesses • Pulmonary complications and vomiting were not different between groups • 25% of PEG recipients attempted to remove the PEG repeatedly <p>The authors recommend that when using a PEG, life expectancy should be at least 3 months, other feeding methods are preferred, patients and relative should participate in decision making, nutrition follow-up should be conducted.</p>	<ul style="list-style-type: none"> • Relied on chart documentation • Method for diagnosing and assessing pressure injuries is not reported • Intervention is poorly described and it is uncertain if all intervention group participants received the same diet/supplement • Co-morbidities not reported • Minimal methods reported 	<p>Level of evidence: 3</p> <p>Quality:</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Harvey et al., 2016	RCT comparing parenteral and enteral nutrition influence on all-cause mortality for critically ill individuals, including pressure injury prevention	<p>Participants were recruited in critical care units in 33 hospitals in the UK (n=2400)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Aged ≥ 18 years Unplanned admission to critical care and expected to commence nutritional support for ≥ 2 days within 36 hours of admission to critical care Expected length of stay in critical care ≥ 3 days <p>Exclusion criteria: contraindications to treatment</p> <ul style="list-style-type: none"> Received nutritional support within preceding 7 days Admitted with PEG or other feeding tube in situ Pregnant Palliative care <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 62-63 years Approximately 57-60% male Similar level of illness severity between groups Mean BMI approx. 26kg/m² 	<ul style="list-style-type: none"> Participants were randomized to receive: <ul style="list-style-type: none"> Early nutritional support via parenteral route via a dedicated central venous catheter lumen (n=1200) or Early nutritional support via enteral route via a nasogastric tube or nasojejunal tube (n=1200) Early nutritional support was delivered for 5 days unless participant transitioned to exclusive oral feeding or was discharged from critical care All participants receiving early nutrition support formula contained 1365 to 2540 total kcal/bag and 7.2–16.0 g nitrogen/bag and goal delivery was 25 kcal/kg/day. 	<ul style="list-style-type: none"> Pressure injury development or worsening assessed while in the critical care unit only Recorded on discharge form as dichotomous yes/no and with Category/Stage 	<p>Adherence 97% of participants received nutritional support within 24 hours</p> <p>Pressure injury outcome measure No significant difference new or substantially worsened pressure injury, with 181 (15.2%) in parenteral group and 179 (15.0%) in enteral group. Effect estimate -0.23 (95% CI -3.10 to 2.64, p=0.91)</p> <p>Primary outcome (mortality)</p> <ul style="list-style-type: none"> No significant difference in 30-day mortality with 393 (33.1%) deaths in parenteral group and 409 (34.2%) deaths in enteral group. Absolute risk reduction 1.15 (95% CI -2.65 to 4.94, p=0.57) Relative risk reduction 0.97 (95% CI 0.86 to 1.08) <p>Author conclusion: There was no difference between parenteral and enteral feeding for all-cause mortality at 30 days.</p> <p>Conclusions: There was also no difference between parenteral and enteral feeding for new or worsened pressure injuries</p>	<ul style="list-style-type: none"> 28% of screened participants were excluded by clinician for unspecified reason reducing generalizability Uncertain how pressure injuries were identified, how often participants were inspected, whether pre-existing PUs were accounted for and whether any training or interrater reliability was conducted for skin assessment Study focuses on effectiveness and cost-effectiveness of routes for nutrient delivery to critically ill people and minimal information on pressure injuries 	<p>Level of evidence: 1</p> <p>Quality: High</p>
Breslow, Hallfrisch, & Goldberg, 1991	Cohort study investigating the nutritional intake and status of people with a PEG with	<p>Participants were recruited in nursing homes in the US over 2 years (n=26)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> All tube fed patients 	<ul style="list-style-type: none"> All participants received standard formula (17% protein, 28% fat, 55% carbohydrate, 	<ul style="list-style-type: none"> Pressure injuries categorized using Shea criteria Dietary intake blood biochemistry (total protein, 	<p>Nutritional intake</p> <ul style="list-style-type: none"> Energy intake was similar between group with and group without pressure injuries (p=0011) Protein intake was significantly higher in the group with pressure injuries 	<ul style="list-style-type: none"> No baseline pressure injury area was reported. Method for measuring pressure 	<p>Level of evidence: 3</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	and without pressure ulcers	<ul style="list-style-type: none"> One group had at least 1 Category/Stage II to IV pressure injuries and the second group had no pressure injury at entry <p>Participant characteristics:</p> <ul style="list-style-type: none"> Patients with pressure injuries were older, more likely to have dementia, more were immobile Patients with pressure injuries had Category/Stages II and III pressure injuries (n=9) and Category/Stage IV pressure injuries (n = 5) 	<p>calculated using Harris-Benedict formula)</p> <ul style="list-style-type: none"> Feeding formula was tube-administered via gravity drip or continuous pump Participants were analysed in groups with (n=14) or without (n=12) pressure injuries at baseline 	<p>albumin, transferrin, hemoglobin, hematocrit, cholesterol, glucose, white blood count, lymphocytes, plasma copper and zinc, serum urea N, serum creatinine), pressure injury incidence and area</p>	<p>(1.4±0.2g/kg versus 0.9±0.1g/kg, p<0.05)</p> <p>Pressure ulcer surface area</p> <ul style="list-style-type: none"> Surface area was positively correlated with energy intake (calories per kilogram body weight) (r=0.59, p<0.04) Surface area was negatively correlated with body mass index (r= -0.70, p<0.03) <p>Conclusions: even when receiving a high calorie, high protein diet, people with PEGs remained malnourished</p>	<p>injuries is not reported</p> <ul style="list-style-type: none"> Small cohort study Minimal methods reported 	
Henderson , Trumbore, Mobarhan, Benya, & Miles, 1992	Prospective cohort study investigating nutritional intake and status of people with a PEG with and without pressure ulcers	<p>Participants were recruited in a hospital in the US (n=40)</p> <p>Inclusion criteria: Medically stable and 100% diet via enteral feeding</p> <p>Exclusion criteria: None stated</p> <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 63.8 years (range 20 to 95) 90% had a neurological injury/disease 65% of participants had pressure injuries at baseline 32.5% coma/vegetative state Mean age 64 years Baseline serum albumin 37 g/L 	<ul style="list-style-type: none"> No participants had air-fluidized mattress No occlusive dressings used Standardized repositioning regimen used All participants were tube fed for a mean of 24.9 months prior to enrolment All participants received standard formula (30–32 En% fat) via intermittent gravity enteral route including nasogastric, gastrostomy or jejunostomy (n=40 commenced, 33 completed) 	<ul style="list-style-type: none"> Pressure ulcer incidence Category/Stage assessed by physician's using unreported methods and categories Mortality Dietary intake Anthropometry (body weight, BMI, mid-arm muscle area, triceps skinfold) Complications (infection) Follow up at 3 months 	<p>Pressure injury healing and incidence</p> <ul style="list-style-type: none"> At baseline, 65% had a one or more pressure injury At 3 months 61% of remaining participants had a pressure injury <p>Other outcome measures</p> <ul style="list-style-type: none"> No changes in weight or BMI Arm muscle and tricep skin fold increased by 7% over 3 months 	<ul style="list-style-type: none"> Reporting does not indicate whether any pressure injuries healed 	Indirect evidence (pressure injury healing and prevention not reported in sufficient detail)

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> Baseline retinol binding protein 47 mg/L Baseline total protein 71 g/L Baseline hemoglobin 114 g/L 					
Peck, Cohen, & Mulvihill, 1990	Retrospective cohort study investigating complications with tube feeding	<p>Participant records in one nursing home in US were reviewed (n=104)</p> <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 87 years 71 to 100% demented patients 56 to 71% physically restrained patients 36 to 66 months in nursing home Some participants had pressure injuries, but the number was not clear 	<ul style="list-style-type: none"> Participants received either: <ul style="list-style-type: none"> Standard formula providing 1500–2130 kcal/day (n=52), or Usual diet providing 1800–2000 kcal/day (n=52) Feed was delivered via any type of feeding tube as 6 feeds/day 	<ul style="list-style-type: none"> Nutritional adequacy and complications Pressure ulcer incidence Retrospective review of 6 months data 	Pressure injury incidence 21% in supplement group versus 13% in control group	Baseline pressure injury incidence was not reported so it is hard to draw conclusions	<p>Level of evidence: 3</p> <p>Quality: Low</p>
Hartgrink et al., 1998	RCT investigating effect of an oral nutritional formula via nasogastric tube on prevention of pressure injuries	<p>Participants were recruited in a hospital in Netherlands (n=149 randomized, 129 participate in trial, 101 remained in study at week 2)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Hip fracture Pressure injury risk score ≥ 8 points <p>Exclusion criteria:</p> <p>Category/Stage II or greater pressure injury</p> <p>Participant characteristics:</p>	<ul style="list-style-type: none"> All participants had a standard hospital mattress All participants had hip fracture surgery Participants were randomized to receive either: <ul style="list-style-type: none"> Formula (1500 kcal/day, 16 En% protein plus standard hospital diet, commenced within 24 hours of surgery and administered as 1L/day via nasogastric tube) 	<ul style="list-style-type: none"> Pressure injury incidence a Category/Stage of pressure injury Pressure injury risk score Blood biochemistry (total protein, albumin, hemoglobin) Dietary intake 	<p>Pressure injury incidence (ITT analysis) Pressure injury (any Category/Stage) incidence was not significantly difference between the two groups at 2 weeks (52% tube supplemented group versus 69% standard diet only, p=0.69) Per protocol analysis also showed no significant difference No significant difference in Category/Stage pressure injuries between the two groups</p> <p>Other outcome measures</p> <ul style="list-style-type: none"> Supplement group had significantly higher energy and protein intake (p<0.001) 	<ul style="list-style-type: none"> Recruitment of participants is poorly reported Methods of randomization, allocation concealment and blinding are not reported Power calculated for sample size of 60 Two physicians reached agreement on Category/Stage of pressure injuries 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> • Mean age 83-84 years • baseline serum albumin 39 g/L • total protein 68-69.6 g/L • Pressure injury risk score indicated that all participants were at high risk of pressure injury • 15.5% had a Category/Stage I pressure injury at baseline 	<ul style="list-style-type: none"> (n=48 commenced, 25 had 1 week treatment, 16 for 2 weeks), or ○ Standard hospital diet (n=53) • Intervention delivered for 2 weeks 		<ul style="list-style-type: none"> • No difference in pressure injury risk score or blood biochemistry at 2 weeks 		
Teno et al., 2012	Cohort study investigating the effectiveness of tube feeding in preventing PU or promoting Healing	<p>Data was collected from the Minimum Data Set (MDS) from 1999 to 2007 (n=3170)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Nursing home resident hospitalised at least once in first year of entry to cohort • Advanced cognitive impairment <p>Exclusion:</p> <ul style="list-style-type: none"> • Death within 2 weeks of baseline MDS • Evidence PEG within 6 months preceding baseline MDS • Existing PU (for prevention analysis) <p>Characteristics:</p> <ul style="list-style-type: none"> • No significant differences in the following demographics between those with/without PU and those with/without PEG: • Age (mean approx. 82 yrs) • Weight loss (22 to 30%) 	<ul style="list-style-type: none"> • Matched cohort analysis with each participant who had a PEG tube matched to 3 participants without a PEG • Used a fixed-effects model to determine if PEG was related to prevention or healing of PU 	<ul style="list-style-type: none"> • Number and stage of stage II or greater PUs recorded quarterly and annually in MDS • PEG insertion during hospitalization 	<ul style="list-style-type: none"> • 461 participants had a PU and a PEG inserted • Risk of new PU stage II or greater when a PEG was present was OR=2.27, 95% CI 1.95 to 2.65 • Risk of a new stage IV PU when a feeding tube was present was OR=3.31 (95% CI 2.14 to 4.89) • Of those who had a PEG inserted, 27.2% of PUs improved compared with 34.6% improving in participants with no PEG (OR=0.66, 95% CI 0.45 to 0.97) • Researchers suggest increased risk may relate to increased diarrhea or increased immobility, but this was not investigated. <p>Conclusions: Feeding tubes (PEG) are not beneficial and may be associated with increased risk of pressure injuries</p>	<ul style="list-style-type: none"> • Relied on completed MDS, unclear how assessments of PU were conducted • Assumed PEG was inserted in an acute care facility 	<p>Level of evidence: 3</p> <p>Quality: moderate</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> Diabetes, CAD,CHF, COPD, cancer, hip fracture 					
Arinzon, Peisakh, & Berner, 2008	Prospective, observational cohort reporting effectiveness of enteral nutrition (EN) in reducing prevalence of PUs in elderly patients with terminal diagnoses	<p>Participants recruited from psychogeriatric wards for patients with terminal diagnoses in Israel (n=167)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> Admitted to one of 3 wards participating in the study Randomised to be included <p>Characteristics:</p> <ul style="list-style-type: none"> Mean age approx. 80 yrs, primarily female (p=ns between groups for age/gender) Approx 70% had CV disease, 21-30% had diabetes mellitus (p=ns between groups for comorbidities) BMI <21kg/m² more frequent in ENG (30% versus 16%, p=0.043) Presence of PU at baseline more frequent in ENG (26% versus 12%, p=0.017) ENG participants had higher levels of dehydration at baseline (26% versus 13%, p=0.028) Significant differences between groups in albumin, transferrin, CRP, BUN/Cr, sodium, potassium, urea nitrogen at baseline 	<p>Two groups were followed:</p> <ul style="list-style-type: none"> Enteral nutrition group (ENG) receiving EN primarily for weight loss (40%) stroke with impaired oral intake (32%), vegetative state (12%), end-stage Parkinson's disease (9%), and malignancy (5%). 74% had NGT, 26% PEG. Most frequent diet was 1800 to 2000 calories, 2 to 3 g sodium and 80 g protein delivered through Osmolite® HN (81% participants). (n=57) Control group (CG) taking a regular oral diet. However, 76% of the group had nutritional supplementation for >2 months during the observation period, usually Ensure®. (n=110) 	<ul style="list-style-type: none"> BMI – 21kg/m² was considered marker of malnutrition PU presence – used staging but did not state the scale PU risk – Norton scale Laboratory values including serum proteins, renal function, cholesterol, iron, folic acid 	<ul style="list-style-type: none"> ENG had significant differences in laboratory values compared with CG. ENG experienced more major complications or symptoms related to nutrition (61% versus 34%, p<0.01) including pneumonia, weight changes, death. <p>PU prevalence</p> <ul style="list-style-type: none"> ENG had high prevalence of stage III to IV PUs at completion of study (14% versus 2%, p=0.005). No significant difference in stage I to II PUs (16% ENG versus 12% CG, p>0.05) Prevalence of PUs overall appears to be 24% CG versus 30% ENG, however analysis compared with baseline differences is not reported. Difference between ENG and CG in mean PU risk assessed on Norton scale was significant at baseline and at the conclusion of study. <p>Conclusions: An EN regimen in older adults with malnutrition and terminal disease states does not appear to influence prevalence of PU or PU risk significantly compared with an oral diet.</p>	<ul style="list-style-type: none"> Groups were significantly different at baseline for primary outcome measures of nutritional state and PU Unclear how PU staging was done Large number of dropouts, primarily due to death (42% in ENG, 27% in CG) No reporting of concurrent management strategies e.g. pressure relieving surfaces. Pollution of control group, 76% of whom also took supplementation for at least 2 months. 	<p>Level of evidence: 3</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical question 7: Nutritional interventional for treating pressure injuries –oral nutritional supplement (ONS) with arginine and micronutrients							
M. D. Banks et al., 2016	Pilot RCT exploring a high protein/high energy supplement with arginine, vit C and zinc for treating pressure injuries	Participants were recruited from a hospital in Australia (n=185 identified, n=50 eligible and randomized) Inclusion criteria: <ul style="list-style-type: none"> Existing Category/Stage 2 or greater PU Exclusion criteria: <ul style="list-style-type: none"> Unable to receive enteral or parenteral nutrition Inappropriate for intensive nutrition support Unable to follow nutritional advice (e.g. cognition level) Participant characteristics: Participant characteristics: <ul style="list-style-type: none"> Median length of stay 14 days (range 1 to 70) Mean age approx. 62-65 years Approx. 20% had BMI <20kg/m² Approx. 40% of participants had > 1 PU Approx. 45% PUs were Category/Stage 2 	<ul style="list-style-type: none"> Participants were randomized (stratified by PU Category/Stage) to receive : <ul style="list-style-type: none"> Standard nutrition care including review by dietitian, standard hospital diet or high protein/energy diet (n=25 randomized, n=17 analyzed) Intensive individualized diet including dietitian, high protein/energy diet aimed at 1.2g protein/kg/bodyweight/day plus 30kcal/kg body weight/day plus enrichment with arginine, vitamin C and zinc (n=25 randomized, n=14 analyzed) 	<ul style="list-style-type: none"> Change from baseline in PU in PUSH score at day 15 Change from baseline in PU size measure using wound tracings of area at day 15 Data collected by research nurse on baseline and days 5,10,15,22 and 29 and then weekly until discharge 	PU outcomes <ul style="list-style-type: none"> There was no significant difference in change in total PUSH score (median change - 3.0, 95% CI -6.5 to -1.5 in standard care versus 4.5, 95% CI -9.0 to 4.0 in intervention group) There was no significant difference in change in PU area in cm² (mean change -1.7cm², 95% CI -7.2 to -0.5 in standard care versus -1.4cm², 95% CI -2.4 to -0.7 in intervention group) Dietitian review Intervention group were more likely to have dietitian review (74% reviewed 2-3 times/week) compared to standard care group (83% had no review)	<ul style="list-style-type: none"> The pilot was designed to test feasibility of study design so not powered to measure an effect The PUs in control group were larger and had greater opportunity for improvement using percent reduction in size Findings provide future guidance on outcome measurement and trial design more than the intervention specifically 	Level of evidence: 1 Quality: Low
E. Cereda, Klersy, Seriola, Crespi, & D'Andrea, 2015	RCT investigating effectiveness of a supplement containing arginine, zinc, antioxidants	Participants were recruited from seven adult long term care services (n=200) Inclusion: <ul style="list-style-type: none"> Stage 2 to 4 PU Malnourished (BMI <20kg.m² or <21 for people ≥65 yrs; recent unintentional weight loss ≥ 	<ul style="list-style-type: none"> Participants' needs determined using Harris-Benedict equation with daily protein need at 1.5g/kg (people with BMI>27 had needs set for ideal weight and BMI 23) In addition to normal diet, participants received ONS 	<ul style="list-style-type: none"> Mean reduction in PU area at 8 weeks PU measured using a licensed wound measurement system that staff had training in (baseline, 4 weeks and 8 weeks) Complete wound healing 	<ul style="list-style-type: none"> Adherence >80% in both groups, no significant difference between groups (p=0.65) Participants withdrew due to death, transfer, gastrointestinal upset[GIT] (no significant differences between groups) 	<ul style="list-style-type: none"> Met adequate enrolment and completion required by power calculation 	Level of evidence: 1 Quality: High

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	in promoting PU healing	<p>10%/3 months; low serum albumin; reduced food intake)</p> <ul style="list-style-type: none"> • Able to drink oral nutritional supplement (ONS) <p>Exclusion:</p> <ul style="list-style-type: none"> • Poorly controlled diabetes, acute organ failure, advanced renal or hepatic disease, moderate to severe heart failure, COPD, PVD, connective tissue disease, neoplasm, hemoglobin <10g/dL, obesity, immunosuppressive therapy • Infected wound, cellulitis, sepsis or osteomyelitis • Any artificial nutrition <p>Characteristics:</p> <ul style="list-style-type: none"> • Mean age 81 years • Mean primary PU area approx. 2200mm² • Primarily sacral PU • Approximately one third each Category/Stage 2 to 4 PUs • Approx. 80% PU duration > 1 month • No significant difference between groups in baseline demographics 	<p>administered in 100ml boluses throughout the day</p> <ul style="list-style-type: none"> • Participants were randomized to receive : <ul style="list-style-type: none"> ○ 2 bottles per day (400ml) of energy-dense, protein-rich ONS with 500kcal and 40g protein. Items significantly different to control: 1.5g arginine, 4.5mg zinc, 675mcg copper, 1.3 mcg manganese, 32 mcg selenium, 19mg vitamin E (n=101, n=78 completed 4 weeks, n=67 completed 8 weeks) ○ Control energy dense, protein-rich ONS containing no arginine, 2.3mg zinc, 338mcg copper, 0.63 mcg manganese, 11mcb selenium 2.3g vitamin E (n=99, n=79 completed 4 weeks, n=71 completed 8 weeks) • ONS delivered for 8 weeks or until PU healed • Participants received evidence-based wound care including pressure relieving devices 	<ul style="list-style-type: none"> • Reduction in wound area of ≥40% at 4 weeks • Incidence of infection • Total number dressing changes in intervention period 	<ul style="list-style-type: none"> • Mean reduction in PU area at 8 weeks <ul style="list-style-type: none"> ○ Experimental 60.9% (95% CI 54.3 to 67.5) versus control 45.2% (95% CI 38.4 to 52.0, p=0.026) ○ Adjusted treatment effect 18.7% (95% CI 5.7 to 31.8, p=0.017) • Complete healing <ul style="list-style-type: none"> ○ Experimental 16.9% (95% CI 8.2 to 25.6) versus control 9.7% (95% CI 2.1 to 17.3, p=0.10) ○ Adjusted treatment effect 2.16% (95% CI 0.88 to 5.39, p=0.097) • No significant differences in wound infections or mean number of dressings • Reduction in wound area of ≥40% at 4 weeks favored experimental group (p=0.02) • Adverse events were not significantly different between groups and included GIT intolerance and dyspepsia 		
Wong et al., 2014	RCT investigating effectiveness of an amino-acid /arginine based supplement in promoting PU healing	<p>Participants were recruited in one hospital in Singapore (n=26 with n=34 PU)</p> <p>Inclusion criteria: Hospitalized ≥ 2 weeks PU Category/Stage 2 or greater (not unstageable or DTI) Aged ≥ 21 years</p>	<ul style="list-style-type: none"> • All participants received nutrition screening and calculation of daily energy/protein requirements • Participants were randomized to receive 2 sachets in 240ml water daily (morning and evening) of: <ul style="list-style-type: none"> ○ Test supplement containing 7.9g carbohydrate, 7.0g of 	<ul style="list-style-type: none"> • Healing assessed as change in Pressure Ulcer Scale for Healing (PUSH) scores • Acetate wound tracings • Does not state who performed wound assessments, but implies specialist wound care 	<ul style="list-style-type: none"> • Both groups achieved reduction in mean wound area over 2 weeks • Control group had greater mean reduction in wound area compared to treatment group (37.5% versus 27.5%, p=not significant) 	<ul style="list-style-type: none"> • Randomization code method not reported • Based power calculation and analysis on per PU rather than per person 	<p>Level of evidence: 1</p> <p>Quality: High</p>

Nutrition: data extraction and appraisals

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		<p>Able to attend follow up post discharge</p> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • HbA1c \geq 7.0% • Parenteral nutrition • Medically unstable or receiving palliative care • Fluid restriction $<$1L/day • Protein restriction • Receiving other supplements • Able to consume $>$70% caloric requirement or 30ml/kg body weight <p>Participant characteristics:</p> <ul style="list-style-type: none"> • Mean age approx. 75-79 years • About 35% well nourished and 50% moderate malnourishment • Approx. 25% diabetes • Mean hospital length of stay approx. 45 days • Mean wound area around 17-20cm² • Mean PUSH score around 12 	<p>arginine, 7.0g glutamine and 1.5g β-hydroxy β-methylbutyrate (HMB), 200mg calcium (n=12 randomized, n=11 analyzed)</p> <ul style="list-style-type: none"> ○ Control sachet of carbohydrate and calcium (n=14 randomized, n=12 analyzed) • Supplement continued twice daily for 2 weeks • Standard wound care 	<p>nurses (all investigators and care staff and participants were blinded)</p>	<ul style="list-style-type: none"> • Average daily healing was similar between groups (treatment group 0.24cm²/day versus 0.31cm²/day for control group) • Treatment group PUSH score decreased significantly compared to baseline at week 1 (p=0.013) and week 2 (p<0.001) • PUSH score in placebo group showed significant reduction at 2 weeks compared to baseline (p=0.009) <p>Author conclusions: amino acid supplement for 2 weeks does not have significant impact on PU healing</p>	<ul style="list-style-type: none"> • Not intention to treat analysis, withdrawals (including deaths) not included • Treatment group had more severely malnourished participants (17% versus 9%) • Length of study is likely insufficient to see significant results 	
Benati, Delveccio, Cilla, & Pedone, 2001	RCT exploring the impact on pressure injury healing of a high-calorie oral nutritional supplements (200 mL each) enriched with arginine (7.5 g/day), zinc	<p>Participants were recruited in a single hospital in Italy (n=36)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Pressure injuries • Severe cognitive impairment (MMSE<15) <p>Exclusions criteria:</p> <ul style="list-style-type: none"> • Patients unlikely to benefit from nutritional supplementation <p>Participant characteristics:</p>	<p>Participants were randomized to one of three groups:</p> <ul style="list-style-type: none"> • Normal hospital diet plus 2 high-protein and high-calorie oral nutritional supplements (ONS, 200 mL each), providing a total of 500 kcal and 37 g/day protein, enriched with arginine (7.5 g/day), zinc (25 mg) and antioxidants (n=12) • Normal hospital diet plus 2 high-protein and high-calorie ONS (200 mL each) providing a 	<ul style="list-style-type: none"> • Pressure Sore Status Tool (PSST) measured at baseline, 5 days, 10 days and 15 days • Unclear who performed measurement and if it was blinded 	<p>Outcome (PSST score)</p> <p>Results are reported only graphically and no effect size</p> <p>Individuals receiving normal hospital diet showed no change in PSST</p> <p>Individuals receiving ONS may have had improvements, but it is unclear if there was any significant effect</p> <p>Conclusions: authors conclude that ONS appeared to improve healing</p>	<ul style="list-style-type: none"> • Limited information on design, possibility to replicate is low • Limited statistical power • Graphical presentation of results makes it hard to quantify effect, no statistical analysis presented 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

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	(25 mg) and antioxidants	Age range 72 to 91 years	total of 500 kcal and 37 g of protein daily (n=12) <ul style="list-style-type: none"> Normal hospital diet (n=12) 		compared to hospital diet, but the data doesn't show significant effect. Authors report a tendency for healing as more evident for ONS enriched with arginine, zinc and antioxidants.	<ul style="list-style-type: none"> No information on funding and conflict of interest. 	
Desneves, Todorovic, Cassar, & Crowe, 2005	RCT to evaluate high protein/high energy oral nutrition supplements (ONS) and ONS plus arginine for promoting healing in pressure injuries.	<p>Participants were recruited from older adult and spinal injury units in Australia (n=16)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Pressure injuries stages 2-4 <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Osteomyelitis, diabetes Enterally fed Receiving hydroxyurea or steroids <p>Participant characteristics:</p> <ul style="list-style-type: none"> Age ranged from 37-97 years BMI ranged from 16.4-28.1 75% of participants had stage 2 pressure injuries 	<ul style="list-style-type: none"> All participants were randomized to one of three interventions: <ul style="list-style-type: none"> Group A received a regular hospital diet (n=6) Group B received a hospital diet plus two high energy/protein ONSs (500 calories, 18 gm protein, 72 mg vitamin C, and 7.5 mg zinc) (n=5) Group C received a regular diet plus two ONSs containing arginine (500 calories, 21 gm protein, 500 mg vitamin C, 30 mg zinc, and 9 g arginine) (n=5) Interventions were provided for three weeks: Participants had an air mattress and was a 2-hour turning schedule. 	<ul style="list-style-type: none"> Blinded assessment of pressure injury condition assessed weekly for 3 weeks using PUSH score Dietary intake measured via 24-hour recall. Intake was analyzed utilizing Australian food and nutrient database. Weights conducted weekly. Height measured via knee height measurement. Laboratory tests weekly including liver function, urea and electrolytes, prealbumin, c-reactive protein, serum zinc and vitamin C. 	<p>PUSH scores over 3 weeks</p> <ul style="list-style-type: none"> Participants receiving ONS plus arginine saw a significant improvement in the overall PUSH score (baseline 9.4± 1.2; Week 2 4.4±1.5, p<0.05; week 3 2.6±0.6, p<0.01) Participants receiving hospital diet only and participants receiving two high energy/protein ONSs showed no significant improvement in PUSH score <p>Dietary intake and weight</p> <ul style="list-style-type: none"> Adherence to ONSs was 94%. While there was no significant difference in overall dietary intake, group C received more arginine, vitamin C and zinc based on intervention composition. No significant weight change in any participants over study period. <p>Laboratory tests at 3 weeks</p> <ul style="list-style-type: none"> No significant change in biomarkers. At baseline and at the end of the study, albumin was low, C- 	<ul style="list-style-type: none"> Very small sample unlikely to be powered to measure significant effect Allocation concealment not reported 	<p>Level of evidence: 1</p> <p>Quality: Moderate</p>

Nutrition: data extraction and appraisals

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					<p>reactive protein was high, and vitamin C and zinc remained low. Positive trend in vitamin C that is not statistically significant.</p> <p>Conclusions: The authors concluded that implementing ONS with supplementary arginine, zinc and vitamin C improved pressure injury healing.</p>		
Heyman, Van De Looverbosch, Meijer, & Schols, 2008	Cohort study exploring oral nutritional supplement (ONS) with micronutrients plus standard care on the healing of pressure injuries in long-term nursing home residents	<p>Participants were recruited over six-month period from 61 long term care facilities in Luxembourg and Belgium (n=245)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Category/stage II–IV pressure injuries <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • None <p>Participant characteristics:</p> <ul style="list-style-type: none"> • Mean age 82.2±10.1 • Pressure injuries primarily sacral (27%) and heel (32%) • 25% Category/stage 2, 26% Category/stage 3, 38% Category/stage 4, 11% not reported 	<p>Residents received the ONS daily for nine weeks, Consisting of 250kcal/20g protein, 3g arginine, 250mg vitamin C, 38mg vitamin E and 9mg zinc plus micronutrients</p> <p>Participants continued to receive routine oral or enteral meals</p>	<ul style="list-style-type: none"> • Pressure injury area was calculated as width and length with a ruler to the nearest millimeter, measured at baseline, 3 and 9 weeks • Pressure injuries condition assessment included presence of clinical signs of topical infection and necrotic tissue and exudate level (subjectively reported as absent, mild, moderate or severe) • Pressure injury condition assessed using an unnamed standardized questionnaire at baseline, 3 and 9 weeks. 	<p>Pressure injury area and condition</p> <p>Significant 53% reduction in pressure injury size was observed at 9 weeks compared with baseline 743 ± 1809mm² versus 1580 ± 3743mm², p<0.0001</p> <p>Exudate significantly decreased after nutritional support(p<0.0001).</p> <p>Complete wound healing</p> <p>At 3 weeks 7% of pressure injuries were completed healed</p> <p>At 9 weeks 20% of pressure injuries were completed healed</p> <p>ONS intake</p> <p>The average intake of the 200ml ONS was 2.3 ± 0.56 servings daily (46g protein, 6.9g arginine, 575mg vitamin C, 87mg vitamin E and 21mg zinc)</p>	<ul style="list-style-type: none"> • The study has several limitations, principally that it is an open multicenter trial and not randomized or placebo-controlled • Does not consider impact of wound care measures on improvements in wound condition • Inter-rater reliability between centers could not be assured • Exudate levels were not measured objectively, and ruler rather than planimetry was used to measure the pressure injury area 	<p>Level of evidence: 3</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence: Quality:
Monteferrario et al., 2013	Observational study evaluating healing of pressure injuries in older adults receiving an oral nutritional supplement (ONS) with arginine and micronutrients	<p>Participants were recruited in a geriatrics department in Italy over a 3-month period in (n=13 recruited, n=11 analyzed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Existing pressure injuries <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Not defined <p>Participant characteristics:</p> <ul style="list-style-type: none"> Age range= 64-96 years 	<ul style="list-style-type: none"> Participants received ONS containing 2gL-arginine, 500mg Omega-3, 100mg vitamin C, 100mg collagen type II, 4mg zinc, 4mg vitamin E, 400µg vitamin A, 0.4mg vitamin B6, 0.25mg vitamin B1, 15µg vitamin K1, and 0.05µg vitamin B12 Number of bags per day (volume not reported) of supplement was determined by Category/stage of pressure injury with 1 bag for stage 1, stage 2 receiving 2 bags and stage 3 and 4 receiving 3 bags. 	<ul style="list-style-type: none"> Evaluation at baseline, 7 and 14 days. PU size measured by unspecified method Nutritional intake, weekly weights, blood test, and the short form MNA were used to measure nutritional status. 	<p>Mean pressure injury area at 14 days</p> <ul style="list-style-type: none"> Statistically significant (p=0.018) reduction in mean wound area over 14 days 63.7% of pressure injuries stage 2 and 3 saw an 18.2% in size after 14 days Increase in stage 1 pressure injuries from 0 to 53.5% seen over 14 days 	<ul style="list-style-type: none"> Poorly described data pressure injury measurement Compliance was defined by number of drop outs rather than quantity of ONS consumed. Very small sample size No confounders identified or discussed Unclear how pressure injuries were measured or by whom the study followed the healing process for wounds in the sacrum, wounds in other locations not considered. 	<p>Level of evidence: 4</p> <p>Quality: Low</p>
Frias Soriano et al., 2004	Prospective cohort study evaluating effectiveness of an oral nutritional supplement (ONS) rich in protein and enriched with arginine, vitamin C and zinc on the healing of	<p>Participants were recruited in 10 hospitals in Spain (n=63 recruited, n=39 reported)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Aged over 18 years with Category/stage III and IV pressure injuries <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Renal or hepatic insufficiency <p>Participant characteristics:</p> <ul style="list-style-type: none"> Primarily sacral pressure injuries 	<ul style="list-style-type: none"> Dietary intake was calculated based on Harris Benedict equation for energy requirements Food intake was evaluated and then an appropriate supplement amount was provided as one to three packages per day of an ONS containing 250kcal energy, 20g protein, 250mg vitamin C, 9mg zinc, vitamin E. In all hospitals wounds were treated according to national 	<ul style="list-style-type: none"> Wound area and the wound condition assessed weekly for 3 weeks Wound healing per day was calculated as: (Wound area at week X - wound area at baseline) / number days between baseline and week X. Days to heal 1cm² was calculated as: Number of days between baseline and week X / (wound area at week X - wound area at baseline) 	<p>Change in wound area over 3 weeks</p> <ul style="list-style-type: none"> After three weeks of supplementation with ONS, median wound area had significant (p<0.001) 29% reduction (23.6cm² (1.6–176.6cm²) to 19.2cm² (1.2–132.7cm²). Median healing of wound area was 0.34cm² per day, taking approximately two days to heal 1cm². Exudate in infected pressure injuries (p=0.012) and the 	<ul style="list-style-type: none"> This study used an open design to test the concept that a specific ONS improves pressure injury healing. Because of this open study design, the results obtained were with historical control data. 38% participants had no wound measurements 	<p>Level of evidence: 3</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	pressure injuries	<ul style="list-style-type: none"> • Mean baseline wound area 23.6cm² (range 1.6 to 176.6cm²) • 62% Grade IV pressure injuries 	guidelines for pressure injury management (GNEAUPP)		incidence of necrotic tissue (p=0.001) reduced significantly.	taken and were not included in analysis	
Wilson, Purushot haman, & Morley, 2002	Repeated measures cohort study exploring influence of liquid nutritional supplements on oral intake in healthy older adults	<p>Participants were health recruits in the US (n=15)</p> <p>Inclusion criteria: Normal cognitive function Satisfactory physical examination No dietary restraint or eating abnormalities At 3 or more regular meals daily No food allergies No medications</p> <p>Participant characteristics: Age range: 15 participants over 70 years and 15 in age range 20 to 40 years Mean BMI was around 23.8 for older and younger participant groups</p>	<p>Pre-study Eat three regular spaced meals daily Keep a food diary for 3 days</p> <p>Participants undertook a range of eating challenges with different preloads including high carbohydrate drink, high protein drink, high fat drink and water. Each preload contains 1255kL energy (except water)</p>	<ul style="list-style-type: none"> • Palatability, hunger, fullness and satiation (time from preload to request for test meal) all measured on 10cm visual analog scale (VAS) • Energy intake including preload • 	<ul style="list-style-type: none"> • After preloads, older participants consumed significantly less energy than did younger subjects (p<0.05). • No difference in ratings for palatability, hunger, fullness between the older and younger cohorts • Interval between preload and request for first meal was longer for older adults after high fat preload (mean 94±3.4 versus 69.5±2.8, p=0.001) • Interval between preload and request for first meal was longer for older adults after high fat preload (mean 72.2±1.6 versus 64.3±1.8, p=0.001) <p>Author conclusions: energy intake is higher when nutritional supplement is administered at least one hour before meals and energy intake is lower for older adults than for younger people after the same supplements</p>	<ul style="list-style-type: none"> • Healthy cohort, uncertain if the results are also applicable to individuals with chronic wounds • Results suggest liquid supplements should be given between meals, at least one hour before the next meal 	Indirect evidence (not population at risk of pressure injury)
Leigh et al., 2012	RCT comparing different doses of arginine for healing PUs	<p>Participants were recruited from acute inpatient and rehabilitation wards from an Australian hospital (n=23)</p> <p>Inclusion: <ul style="list-style-type: none"> • Category II, III or IV PUs showing no sign of healing </p>	<p>All participants had standard PU care throughout study.</p> <p>Participants were randomized to receive either:</p> <ul style="list-style-type: none"> • Standard hospital diet plus 4.5 g arginine daily for 3 weeks (n=12) or 	<ul style="list-style-type: none"> • Healing rate of PU size and severity assessed weekly using by PUSH tool • Nutritional status assessed on Subjective Global Assessment <p>Follow up at 3 weeks</p>	<ul style="list-style-type: none"> • There was a significant decrease in PU severity over time (p<0.001) with no evidence of difference in healing rate between the two arginine dosages (p=0.991) • Based on expected healing time, patients in both treatment groups were estimated to 	<ul style="list-style-type: none"> • No active control group and • No stratification or monitoring of arginine levels • There were no differences in healing rates of PU with arginine doses 	<p>Level of evidence: 1</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

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		<ul style="list-style-type: none"> Oral diet without arginine supplement <p>Exclusion:</p> <ul style="list-style-type: none"> Acute GIT surgery Sepsis Dialysis Receiving hydroxyurea or >10mg daily prednisolone or 1.5mg daily dexamethasone <p>Characteristics:</p> <ul style="list-style-type: none"> No significant differences in characteristics between groups at baseline Mean age 67 to 69 yrs Mean BMI approx 26.8 Primarily category II PUs Baseline PUSH scores for the two groups similar 8.9 ± 0.7 (4.5g) versus 8.1 ± 1.0; (9g), p=0.507 	<ul style="list-style-type: none"> Standard hospital diet plus 9g arginine daily for 3 weeks (n=11) <p>Patients who were discharged before the end of the study were given the appropriate number of arginine supplements and reviewed at the nearest wound clinic at the end of the study period</p>		<p>achieve an almost 2-fold improvement compared with the historical control group</p> <ul style="list-style-type: none"> Participants categorized as malnourished showed clinically significant impaired healing rates compared with well-nourished patients (p=0.057) although this was unaffected by arginine dosage (p=0.727) There was no significant difference in healing rates based on arginine dosage (p=0.393) Concordance was 92% of participants, with no difference between groups <p>Conclusions: Arginine was associated with increased healing compared with historical controls, with no difference noted between a 4.5g daily and a 9g daily dose of supplementation.</p>	<p>however it is a valid question would be if such healing rates differed from the normal rate of healing of PUs</p> <ul style="list-style-type: none"> Healing rate was monitored over a 3 week period rather than as time-to-healing data No wound measurement or digital planimetry to objectively assess healing 	
Brewer et al., 2010	Historical control study investigating the effect of arginine supplementation in promoting healing of PU in community SCI patients	<p>Participants were recruited from through a SCI community support group in Australia (n=18) and database from spinal nurse of same group was used to attain control group (n=17)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> SCI Aged ≥ 18 years Category II, III or IV PU <p>Exclusion:</p> <ul style="list-style-type: none"> Phenylketonuria Sepsis Chronic renal failure 	<p>Intervention group (n=18): Consumed x2 sachets daily of supplement containing 4.5g arginine, 4g carbohydrate, 155mg vitamin C, 50mg vitamin E. Sachets consumed in 200 to 250 ml water.</p> <p>All other care was according to recommended guidelines.</p>	<ul style="list-style-type: none"> PU size and severity assessed using PUSH tool Nutritional status assessed on Subjective Global Assessment 	<ul style="list-style-type: none"> The intervention group showed superior healing with respect to time to complete healing compared to the control group (10.5±1.3 wks versus 21.1±3.7 wks, p=0.006) There was no significant difference in healing rates between participants with and without diabetes in the intervention group (p=0.894) or between participants with and without diabetes in the historical control group (p=0.994) All participants in intervention group consumed at least 85% of 	<ul style="list-style-type: none"> Relied on database information for control group Nutritional status of control group was unavailable Small sample size 	<p>Level of evidence: 4</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> Metabolic disease Diabetic foot ulcer Suspected osteomyelitis Receiving hydroxyurea or >10mg daily prednisolone or 1.5mg daily dexamethasone <p>Characteristics:</p> <ul style="list-style-type: none"> Participants were matched for age, gender, level of SCI injury, baseline PUSH, baseline PU area Baseline PU area was 4.5 to 6.7 cm² Mean age was 49.9 to 52.2 			<p>supplement doses until full healing was achieved.</p> <p>Conclusions: arginine supplementation of 9g daily may be associated with faster PU healing in patients with SCI with and without diabetes</p>		
Chapman, Mills, Pearce, & Crowe, 2011	Observational study investigating PU healing in SCI patients receiving arginine supplements	<p>Participants were recruited from inpatient and outpatient services in Australia (n=34)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> Over 18 years age At least one PU of at least stage II severity Able to receive oral nutritional support <p>Characteristics:</p> <ul style="list-style-type: none"> Age range 18 to 71 years Primarily admitted for management of PU Primarily stage III PUs 	<p>In addition to standard diet, all participants were prescribed 237 mL x 2 daily of a supplement containing 18 g protein, 9 g arginine, 30mg zinc and 500 mg vitamin C.</p> <p>All participants received nutritional counselling and dietitian review weekly and if supplementation was < 75% prescribed dose for 3 consecutive days, participant was offered an alternative high protein without micronutrients.</p>	<ul style="list-style-type: none"> Nutritional status classified as well-nourished or undernourished based on BMI, weight and diet history, clinical factors and impacting nutrition) PU healing assessed via measurement and classification according to EPUAP classification criteria PU condition assessed using PUSH Scale for Healing tool Wound assessments conducted weekly 	<ul style="list-style-type: none"> 41% of participants ceased the supplement prior to full healing, there was no significant difference in demographics between participants who ceased or completed supplementation No difference in time to healing of grade III PUs between those who ceased treatment (mean 14.3±7.3 wks) and those who completed (11.4±2.0 wks, p=ns) No difference in time to healing of grade IV PUs between those who ceased treatment (mean 31.3±13.6 wks) and those who completed (11.4±2.0 wks, p=ns) A 2.5 fold greater rate of healing was observed in those who completed supplementation until full healing compared with those who ceased taking the supplement when healing of grade III and IV PUs was 	<ul style="list-style-type: none"> Small study with no control group Co-morbidities that may influence healing were not reported 41% of participants did not tolerate supplement Non-blinded assessment of PU healing Concurrent management not reported Multi-site study that did not report comparisons by site 	<p>Level of evidence: 4</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					<p>combined (8.5±1.1 wks vs. 20.9±7.0 wks, p=0.04)</p> <ul style="list-style-type: none"> • Conclusions: an arginine supplement (9 g daily) may be associated with improved PU healing rates in SCI patients with grade III and IV PUs 		
van Anholt et al., 2010	double-blind RCT investigating a high protein, arginine and micro-nutrient rich supplement to improved PU healing in adults of normal nourishment	<p>Participants recruited from 8 health care centres, hospitals, and long term care facilities in 4 European countries (n=43)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Aged 18 to 90 years • At least one stage III or IV PU according to EPUAP classification • Receiving standard care and diet without supplements for at least 2 weeks <p>Exclusion:</p> <ul style="list-style-type: none"> • Malnourished (BMI <18.5kg/m² if aged 18 to 70 or 21kg/m² if aged over 70 years) • Medical condition that would influence healing • Ulcer of different aetiology • Palliative care • Protein restricted diet • Corticosteroids <p>Characteristics:</p> <ul style="list-style-type: none"> • No significant difference in baseline characteristics between groups • Mean age 73 to 76 years • Mean BMI 23.7 to 25.8 • Primarily bed or chair bound with very limited mobility 	<p>Participants were randomly allocated to either:</p> <ul style="list-style-type: none"> • High energy oral nutrition supplement enriched with protein (20 g) arginine (3 g), antioxidants, vitamins A, E and C, zinc (9 mg), copper (1.35 mg), selenium (64 µg) and folic acid (200 µg) of 200ml x3 daily between meals for 8 weeks (ONS group, n=22) or • Non-caloric flavoured placebo 200ml x3 daily between meals for 8 weeks (control group, n=21) 	<ul style="list-style-type: none"> • PU healing assessed by the change in surface area over 8 weeks (measured with ruler weekly) • PUSH tool score change over 8 weeks (recorded weekly) 	<ul style="list-style-type: none"> • At 8 weeks there was a statistically significant difference in decrease in PU size between groups (p=0.006 treatment by time, p=0.016 treatment by time², repeated-measures mixed models [RMMM]) • PUs in ONS group were significantly smaller compared with baseline by week 3 (p=0.019, ANOVA) and continued to be improved (p≤0.012, ANOVA) • PUs in control group showed significant improvement compared with baseline from week 5 (p=0.019) and continued to show improvements (p≤0.008) • ONS group had significant improvement in PUSH score compared with control group (p=0.033, treatment by time², RMMM) <p>Conclusions: a nutritional supplement with high protein, arginine and micronutrients may be associated with improved PU healing in older adults who do not have pre-existing malnourishment</p>	<ul style="list-style-type: none"> • Concurrent management strategies are not reported and it is unclear if this is consistent between 4 countries • Comparison of results by site is not reported 	<p>Level of evidence: 1</p> <p>Quality: Moderate</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> • Primarily stage III PUs • Baseline PU size approx. 11cm² 					

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Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical question 7: Nutritional interventional for treating pressure injuries –other nutritional supplements							
(Sakae, Agata, Kamide, & Yanagisawa, 2013)	Quasi-experiment determine if L-carnosin (CAR) or Zinc complex Polaprezinc (PLZ) as an oral nutritional supplement would improve pressure injury healing rates compared to standard treatment	<p>Participants were recruited from two long term care facilities in Japan (n=42)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Aged ≥20 years • stage II, III or IV pressure injury that is more 4 weeks duration • estimated surface area of ≤24cm² • Able to eat orally <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Clinical suspicious of osteomyelitis • Diabetes mellitus, peripheral vascular disease, acute illness, malignant tumors, terminal illness, corticosteroid usage • Tube or parenteral feeding <p>Patient characteristics:</p> <ul style="list-style-type: none"> • No significant difference in all arms of the study in terms of demographics, nutritional parameters, pressure injury risk and PU characteristics, except for PU location. • PUSH score average 10.7-11.6 • BMI average 16-17 • Average age 61-68 	<ul style="list-style-type: none"> • All participants received local treatment of repositioning frequently, alternating pressure air mattress • All participants received surgical debridement, sucrose + povidone iodine and hydrofiber plus polyurethane foam, done 10-14 days before surgery if required. • All patients were randomized to one of three groups: <ul style="list-style-type: none"> ○ L-carnosin (CAR) group received 116mg/day of CAR; blood works done at week 4 (n=18) ○ Zinc complex Polaprezinc (PLZ) group received 150mg/day of PLZ ; blood works done at week 1-4 (n=10) ○ Received standard treatment with blood works at week 4. (n=14) 	<ul style="list-style-type: none"> • Staging follows EPUAP and NPUAP guidelines • Healing rates determined by PUSH score which is calculated weekly • Assessment of nutritional intake, pressure injury characteristics and blood biochemistry were compared at start of trial and end of 4 weeks. 	<p>Change in body weight and dietary intake</p> <p>No statistical difference in body weight and dietary intake among all groups at 4 weeks.</p> <p>Pressure injury assessment</p> <ul style="list-style-type: none"> • PUSH score was significantly greater in the CAR (1.6 ± 0.2, $P = .02$) and PLZ groups (1.8 ± 0.2, $p=0.009$) compared with control group (0.8 ± 0.2). • There is no significant difference between CAR and PLZ group PUSH score. ($p=0.73$). <p>Blood biochemistry</p> <ul style="list-style-type: none"> • CAR group: no change in serum Zn, Cu or Fe. • PLZ group: showed significant increase in serum ZN but Cu levels significantly decreased and there was no difference in Fe levels. • Serum transthyretin and albumin levels were below reference range (transthyretin, 22–40 mg/dL; serum albumin, 3.8–5.3 g/dL) while CRP was above reference range (≤ 0.30 mg/dL) in all three groups. • Complete blood count, renal panel, uric acid, total and HDL did not have significant changes. <p>Author conclusions: serum CAR and PLZ supplement may play a role in the improvement of PUSH scores but the baseline blood biochemistry markers, BMI and dietary intake indicates that the population is still malnourished. High caloric supplements may still be required.</p>	<ul style="list-style-type: none"> • Baseline characteristics are similar for all but several participants were taking nutritional supplements prior to starting the trial. • Psychiatric patients in a hypercatabolic state and are included in the study may have higher nutritional requirements than others. There was no mention if they were compliant to the treatment given. • A randomised controlled trial with a larger population can be useful in assessing the effectiveness of the treatments. 	<p>Level of evidence: 2</p> <p>Quality: Low</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence: 1 Quality: Low
Yamanaka, Okada, & Sanada, 2017	RCT investigating whether collagen peptide oral supplement promotes PU healing	<p>Participants were recruited from 22 facilities in Japan (n=66)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Able to consume $\geq 60\%$ caloric requirement calculated using Harris-Benedict equation • PU present • PU depth into subcutaneous tissue or muscle, tendon or bone • No local or systemic infection • slough $\leq 1/3$ area after debridement <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • PU treated with growth factors • Hepatic or renal dysfunction • Hemodialysis • C-reactive protein $\geq 3.0\text{mg/Dl}$ • HbA1c $\geq 8.0\%$ • VLU present • Aspiration pneumonia during trial <p>Participant characteristics:</p> <ul style="list-style-type: none"> • Mean age between 76 and 79 years • Mean BMI approx. 18-19kg/m² • Mean caloric intake 1390 to 1470 kcal/day • Braden score mean 12-14 	<ul style="list-style-type: none"> • Participants were randomized to one of 3 groups: <ul style="list-style-type: none"> ○ Usual care (n=22 randomized, n=16 analyzed) ○ Collagen peptide drink once daily (80 kcal, 12g protein, 10g collagen peptide) (n=22 randomized, n=18 analyzed) ○ Arginine drink once daily (100 kcal, 5g protein, 2.5g collagen peptide) (n=22 randomized, n=17 analyzed) • Intervention was implemented for 4 weeks • Standard local wound care (with or without antimicrobials) for all participants • 2 hourly repositioning 	<ul style="list-style-type: none"> • Healing assessed as total score on DESIGN-R tool administered at baseline and weekly for 4 weeks during study • Healing assessment conducted by a WOCN and physician 	<ul style="list-style-type: none"> • All groups achieved reductions in mean DESIGN-R scores over 4 weeks • No significant difference in nutrition status among the 3 groups through the study (as determined by blood results) • The collagen peptide group achieved significantly lower DESIGN-R total scores compared to the control groups at week 2 ($p=0.022$), week 3 ($p=0.029$), week 4 ($p=0.027$) • One participant receiving arginine supplement was withdrawn due to bilateral femur swelling, skin redness/heat and diarrhea <p>Author conclusion: Collagen peptide supplement facilitates PU healing over 4 weeks when measured using the DESIGN-R tool</p>	<ul style="list-style-type: none"> • Failed to recruit sufficient participants to meet conservative power calculation • Not a true intention to treat analysis (excluded those with protocol violations) meaning 22% participants not analyzed • Unclear if PU assessment was blinded 	Level of evidence: 1 Quality: Low
Norris & Reymolds, 1971	Cross-over quasi experiment	Participants were recruited in a US chronic diseases hospital	<ul style="list-style-type: none"> • Participants were divided into two 	<ul style="list-style-type: none"> • Pressure injury volume measured using compressions made by 	<p>Change in pressure injury volume</p> <p>There was no significant difference in pressure injury volume between placebo and zinc</p>	<ul style="list-style-type: none"> • Standardized treatment was not 	Level of evidence: 2

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	evaluating zinc sulfate for healing pressure injuries	(n=14 commenced, ONLY n=3 completed) Inclusion criteria: Not stated Exclusion criteria: <ul style="list-style-type: none"> • Neoplasm • Terminal illness • Superficial pressure injuries • Pressure injuries with deep sinus tract Participant characteristics: <ul style="list-style-type: none"> • Age range 26 to 88 years • Range of conditions including brain disorders, neurological impairment and paralysis, polio • Size and duration of pressure injuries not reported 	groups to receive either: <ul style="list-style-type: none"> ○ Zinc sulfate 200mg three capsules per day, or ○ Placebo three capsules per day <ul style="list-style-type: none"> • Participants were crossed into the alternative group after 12 weeks of treatment for the comparison • Participants continued to receive frequent repositioning, antibiotics and local therapy 	filling cavity with alginate hydrocolloid (method has accuracy within 1-2 ml for small ulcers and 2-5ml for large ulcers) <ul style="list-style-type: none"> • Unclear who performed the evaluation • Outcome measured every 4 weeks 	sulfate (net reduction 6.ml placebo vs net reduction 10.1ml zinc, p>0.7) The authors considered that more research is required.	used due to the cross over design <ul style="list-style-type: none"> • Cross-over design fails to account for healing progress and pressure injuries healing more rapidly in first phases of healing • patients receiving placebo in 2nd phase who healed were considered to have "spill over" so were not analyzed • Completion rate of only 21% of participants: 50% died despite not being terminal • Condition of pressure injuries unclear • treatments were inconsistent (e.g. some had antibiotics) 	Quality: Low
Taylor, Rimmer, Day, Butcher , & Dymock, 1974	Controlled trial evaluating ascorbic acid for healing pressure injuries	Participants were surgical patients with pressure injuries recruited in unknown location (n=20) Inclusion and exclusion criteria: <ul style="list-style-type: none"> • Not reported Participant characteristics: <ul style="list-style-type: none"> • About half were neck of femur patients, others had a large mix of diagnoses • Age range 54-88 years 	<ul style="list-style-type: none"> • All participants had standard hospital mattress, basic hospital diet and similar local pressure injury care • Participants received either: <ul style="list-style-type: none"> ○ 500mg ascorbic acid (n=10) administered twice daily, or ○ Placebo twice daily (n=10) 	<ul style="list-style-type: none"> • Subjective assessment of pressure injury by the research team • Wound tracings • Weekly photographs 	Percent wound area reduction at 4 weeks <ul style="list-style-type: none"> • Group receive ascorbic acid showed significantly better mean percent reduction in wound area than the placebo group (84%±7.6 vs 42.5%±7.41, p<0.005) 	<ul style="list-style-type: none"> • Methods of group assignment was not best practice • No reporting of allocation concealment • Blinded trial, however assignment was based on year of birth so blinding was potentially broken 	Level of evidence: 2 Quality:

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> Mean haemoglobin at commencement was 11.1g/100ml Size and duration of pressure injuries not reported 					
Lee, Posthauer, Dorner, Redovian, & Maloney, 2006	RCT to evaluate a concentrated fortified collagen protein hydrolysate supplement for healing pressure injuries	<p>Participants were recruited in long term care facilities in US (n=89 recruited, n=71 completed study and analysed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Category/Stage II to IV pressure injuries <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Terminal or in hospice care Protein restricted diet due to renal insufficiency Active metabolic or gastrointestinal disease Food allergies Corticosteroids or antibiotics 65% of treatment group and 51% control group had Stage II pressure injuries 	<ul style="list-style-type: none"> Participants were randomized to receive either: <ul style="list-style-type: none"> fortified collagen protein hydrolysate supplement containing 15g hydrolyzed protein per 45ml does, three times daily either orally or by feeding tube (Pro-Stat®, n=44) or Placebo (n=27) Kilocalorie and protein intake calculated from determining 3 day food intake before study commenced Intervention for 8 weeks Participants also received enriched foods, commercial supplements, topical pressure injury care and preventive strategies 	<ul style="list-style-type: none"> Blood, urea nitrogen, creatinine measured weeks 3, 4,7,8 PUSH score reported every 2 weeks Adverse events 	<p>Change in PUSH scores at week 8</p> <ul style="list-style-type: none"> Healing rate was significant in both groups over time Healing at week 2 was significantly greater in the treatment group compared to placebo (mean score 7.59±4.85 versus 5.3±4.2, p<0.05) Healing at week 6 was significantly greater in the treatment group compared to placebo (mean score 4.55±5.28 versus 3.78±4.66, p<0.05) Healing at week 8 was significantly greater in the treatment group compared to placebo (mean score 3.55±4.66 versus 3.22±4.11, p<0.05) At 8 weeks the treatment group had a 60% reduction in PUSH score versus 48% in control group, p<0.05) 	<ul style="list-style-type: none"> Methods of randomization and concealment were not best practice Did not report change in pressure injury size Comparability of pressure injuries with respect to duration and size at baseline was unclear Unclear but appears more than one pressure injury per person was analysed 	<p>Level of evidence: 1</p> <p>Quality: Low</p>
Meaume et al., 2009	Double blind RCT investigating	Participants were recruited from 67 European centres. (n=160)	All participants received wound care according to French guidelines, heel	<ul style="list-style-type: none"> Heel PU area reduction assessed via clinical description, acetate 	<p>Participants with baseline PU ≤8cm²</p> <ul style="list-style-type: none"> mean decrease in PU area at week 6 was significantly greater in OKG group versus 	<ul style="list-style-type: none"> Uneven distribution of PU severity between 	<p>Level of evidence: 1</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Quality:
	effectiveness of ornithine alphaketoglutarate (OKG) in promoting healing of heel PUs in older adults	<p>Exclusion:</p> <ul style="list-style-type: none"> Bed-bound prior to PU PU entirely covered by necrosis or fibrin, or infected Poorly controlled diabetes Dialysis Neoplasm Parenteral nutrition Serum albumin <22g/L Advanced peripheral arterial disease <p>Characteristics:</p> <ul style="list-style-type: none"> OKG group had significantly more females than control, otherwise the groups were matched for age (mean 80.8±8.8 yrs), BMI (mean 26.9±6.2 kg/m²) Braden score (mean 17.82±3.2) Placebo group had higher proportion of smaller PUs (52% versus 25.9% with area ≤4cm², p=0.044) 	<p>offloading, pain management, protein intake of 1.2 to 1.5 g/kg/day. Participants were randomised to receive either:</p> <ul style="list-style-type: none"> 10g sachet of OKG administered once daily in 200ml water during or after lunch (n=85) Placebo sachet administered once daily in 200ml water during or after lunch (n=75) <p>No participants had concurrent vitamin C, high dose zinc, amino acids or omega-3 fatty acids during the study. Treatment was for 6 weeks</p>	<p>tracings and measurement of length/width</p> <ul style="list-style-type: none"> Braden score Mini nutritional assessment scale Laboratory values 	<p>placebo group (-2.3±4.2cm² versus -1.7±1.7cm², p=0.006)</p> <ul style="list-style-type: none"> closure rate at week 6 was significantly higher in OKG group versus placebo group (-0.07±0.11cm²/day versus -0.04±0.08cm²/day, p=0.007) Difference in closure rate was attributed to higher closure rates in first 2 weeks of study <p>Participants with PU area > 8cm²</p> <ul style="list-style-type: none"> no difference between groups in mean decrease in PU area. no difference between groups closure rate. <p>Clinically relevant adverse effects Higher incidence of GIT complaints including diarrhoea, vomiting or nausea in OKG group versus placebo (7 considered to be related to treatment, none considered to be severe)</p> <p>Conclusion: The results suggest that OKG supplementation in older adults may contribute to faster healing rates in smaller PUs, particularly in the first 2 weeks of therapy.</p>	<p>groups at baseline leading to analysis by sub group based on 8cm² cut-off to create homogenous groups</p> <ul style="list-style-type: none"> No reporting of difference between sites, however care was standardised 	Quality: High
Theilla et al., 2012	Prospective RCT investigating the impact of fish oil enriched diet on healing of PUs	<p>Participants were recruited from an ICU in Israel. (n=40)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> Nutritional support for ≥ 5 days Grade II or more severe PU according to NPUAP classification <p>Exclusion:</p> <ul style="list-style-type: none"> Immuno-impairment (e.g. AIDS, autoimmune diseases) Immunosuppressives 	<p>Participants received enteral nutrition, or if this was not tolerated, parenteral nutrition. Quantity of formula was based on non-fasting resting energy requirements.</p> <p>Randomised to receive either:</p> <ul style="list-style-type: none"> fish oil and micronutrient-enriched formula (EN was 	<ul style="list-style-type: none"> PU state measured at baseline then weekly for 4 weeks using PUSH tool with 0=healed and 17=worst score Acute inflammation as assessed through serum C-reactive protein (CRP) measured weekly 	<ul style="list-style-type: none"> There was no significant difference in protein intake between the two groups. Fatty acids intake was significantly higher in the study group (p<0.001) Severity of PUs as indicated by PUSH score increased significantly over time for the control group (p=0.02) but not for the study group. The study group had significantly greater decrease in CRP concentrations than the control group (p=0.02). <p>Conclusions: a fish oil and micronutrient-enriched formula may prevent worsening PUs</p>	<ul style="list-style-type: none"> Small sample size No objective measurement of PUs to indicate % wound healing or time to complete healing Person assessing PU severity was not blinded 	<p>Level of evidence: 1</p> <p>Quality: Moderate</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<p>Characteristics:</p> <ul style="list-style-type: none"> • No significant between group differences in age, gender, BMI, duration in ICU, diagnostic category. • Mean age 49 to 53 years • Mean BMI 28 to 32 • Primarily medical and trauma patients • 1/20 in treatment group and 2/20 in control group had a pre-existing PU on admission to ICU and remaining PUs developed after a mean of 6 days (no difference between groups) • No significant difference in PU severity at baseline (primarily grade II, p=0.02) 	<ul style="list-style-type: none"> • enriched with vitamins A, C, E, zinc, manganese, copper, protein) (study group, n=20) or • an isonitrogenous formula (control group, n=20) <p>Parenteral nutrition formulas taken by study and control group participants were not different with respect to micronutrients (but were different for fatty acids).</p>				

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Nutritional interventions for preventing and treating pressure injuries– hydration							
(Li, Kato, Matsuoka, Tanaka, & Miwa, 2013)	Retrospective cohort study reporting the clinical effectiveness of wound healing for people with pressure injuries using hydrogen water via tube feeding	<p>Participants recruited from a hospital long-term care facility in Kobayashi Hospital, Japan (n=22)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Institutionalized patients of a long-term care facility • Impaired mobility • Require assistance with nutritional needs • Category/stage II or III pressure injury • ≥ one co-morbidity <p>Exclusion criteria: None reported</p> <p>Participant characteristics:</p> <ul style="list-style-type: none"> • Mean age 86.7±8.2 years (range 71- 101 years) • Admitted for pressure injury, tumor, COPD, pneumonia or CIS • Average hospitalization days 113.3 to 155.4 • Average length of stay 113-155.4 days 	<ul style="list-style-type: none"> • All participants received routine skin care, pressure relief and nutritional support • Participants were analyzed in groups of: effective group(EG) or less effective based on outcomes of treatment • Effective treatment group received standard treatment with 600ml of hydrogen water in the morning and afternoon to be finished within one hour (n=12) • The less effective group (LG) only received standard care (n=10) 	<ul style="list-style-type: none"> • Wound size was as depth and area. • Digital photography and for recording the shape and outline of wound. • DESIGN-R tool used to assess the pressure injury monthly by hospital staff • Staging done using guidelines from EPUAP/NPUAP • Follow up period was not specifically , length of hospitalization was an outcome 	<p>DESIGN-R tool pressure injury assessment</p> <ul style="list-style-type: none"> • DESIGN-R tool score decreased when comparing onset with endpoint (death or discharge) for the EG group (11.5 rates vs. 14.3 rates, p < 0.05) but no statistical difference for the LG group. <p>Pressure injury size</p> <ul style="list-style-type: none"> • Both the EG and LG had reduction in wound size following the interventions (EG 91.4%, p<0.05) versus LG (48.6%, p<0.001) • EG group achieved significantly better reduction in wound size (p<0.05) <p>Length of hospitalization in relation to DESIGN-R tool evaluation of pressure injury</p> <ul style="list-style-type: none"> • Length of stay in the EG was shorter than the LG (113.3 days vs. 155.4 days, p<0.05) • Category/stage II pressure injuries had shorter length of stay for the EG versus LG (87.5 days vs. 387.0 days, p < 0.001) • No statistical significance difference for hospitalized days for Category/stage III pressure injuries process <p>Author conclusion: hydrogen water has a role in supplementing to achieve pressure injury healing.</p>	<ul style="list-style-type: none"> • Good follow up time frame • Very small study size with no power to measure changes in wound size • Participants had multiple pressure injuries that appear to have all been included in the analysis 	<p>Level of evidence: 3</p> <p>Quality: Low</p>
Stotts et al., 2009	Prospective RCT investigating effectiveness of supplemental	<p>Participants recruited from 5 nursing homes in US (n=53)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Nursing home resident • Braden Scale ≤18 • BMI 20 to 29.5 kg/m² 	<p>Participants randomised to:</p> <ul style="list-style-type: none"> • Usual prescribed fluid prescribed by dietician (control group, n=27) • Supplemental fluid with target volume of fluid 	<p>Potential to heal assessed through measurement of:</p> <ul style="list-style-type: none"> • collagen deposition was measured with 	<ul style="list-style-type: none"> • few participants in this study had PUs and so the effect of supplemental fluid on skin oxygen levels adjacent to the ulcer could not be determined • PU prevalence was 5.6% of participants 	<ul style="list-style-type: none"> • Strict inclusion criteria lead to over 2,00 participants not meeting inclusion criteria 	<p>Level of evidence: 1</p> <p>Quality: High</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	fluid in preventing PUs in older adults	<ul style="list-style-type: none"> WBC $\geq 2,000/\text{nm}^3$ <p>Exclusion:</p> <ul style="list-style-type: none"> Heart failure, kidney disease, tobacco use, acute illness, immunosuppressive medication, Implantable defibrillator Known or suspected dehydration <p>Characteristics:</p> <ul style="list-style-type: none"> Mean age 79.3 ± 8.79 Mean BMI 25.2 ± 2.56 Mean Braden score 14.0 ± 2.31 Three pressure injuries present at baseline, all in treatment group 	prescribed by dietician plus 10 mL/kg body weight administered daily for 5 days, the target volume was divided into 3 doses given orally or NGT (n=26)	<p>Hyp form ePTFE tubes</p> <ul style="list-style-type: none"> Subcutaneous tissue oxygen Estimated total body water <p>Pain measured on Present Pain Intensity Scale of the McGill Pain Questionnaire</p> <p>Fluid overload (measured through lung auscultation)</p>	<ul style="list-style-type: none"> participants potential to heal as measured with Hyp (Collagen) was low at baseline when they took fluids freely and did not increase significantly during the treatment (additional fluid systematically provided) the additional fluid did not result in adverse outcomes including change in lung sounds, extra heart sounds or result in emergency department visits or hospitalization fluid administered based on PsqO2 values resulted in greater fluid being administered to those with low PsqO2 and subsequent work shower greater fluid administered resulted in higher Hyp (collagen) levels; 		

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Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Cost effectiveness studies							
M. D. Banks, Graves, Bauer, & Ash, 2013	Economic modelling to predict the cost of preventing pressure injuries and the potential cost savings associated with nutrition support	Analysis reviewed discharges 2001-2003 in public hospitals in Australia (n=241,415 discharges) Inclusion criteria: <ul style="list-style-type: none"> Economic modeling was conducted on a random sample of 1,000 discharges Exclusion criteria: <ul style="list-style-type: none"> None 	Proposed nutritional support was not described in detail	Analysis considered <ul style="list-style-type: none"> rate of pressure injuries effect of pressure injury on hospital length of stay hospital cost per patient day cost associated with providing intensive nutrition support 	Costs associated with nutritional interventions <ul style="list-style-type: none"> The mean decreased length of stay- 0.52%. 95.1% of individuals with an intensive nutrition support program produced overall cost savings in care Model predicts cost savings of over \$5 million AUD associated with intensive nutritional support Author conclusions: Predictive economic modeling suggests large cost savings associated with providing at risk individuals with intensive nutritional support	<ul style="list-style-type: none"> The study uses data from 2002-2003 Estimates of costs are from 2005 The economic estimates are based on a meta-analysis of five small studies. The assumption that the individuals identified at risk for developing pressure injuries were also malnourished. 	Level of evidence: N/A Quality: Moderate
E. Cereda, Klersy, et al., 2017	Economic evaluation of an RCT to analyze if a high caloric, high protein oral nutritional supplement (ONS) will improve PI healing rates and result in cost savings compared to isocaloric, isonitrogenous formula would result in cost savings	Participants were part of a multicenter, 2-armed RCT conducted at 7 sites in Italy (n=138) Inclusion criteria: <ul style="list-style-type: none"> Adult in long-term care or home care services Able to take oral supplements for 8 weeks Diagnosed with stage II, III or IV pressure injury Malnutrition as diagnosed by BMI, albumin age-specific threshold, unintentional weight loss and energy intake. Exclusion criteria: <ul style="list-style-type: none"> Not reported 	Participants received either: <ul style="list-style-type: none"> high-calorie, high protein ONS enriched with arginine, zinc and antioxidants (n=67) or Isocaloric, isonitrogenous formula (n=71) 	<ul style="list-style-type: none"> Primary outcome measured is the percentage of change in pressure injury after 8 weeks. Secondary end-point is cost analysis. Calculation of the direct medical cost of local pressure injury management between experimental and control group, incremental cost effectiveness ratio (ICER) related to primary clinical outcome. Staging system used was not elaborated in this paper, which 	Pressure injury outcomes <ul style="list-style-type: none"> <i>N.b. the clinical effectiveness results for this study are reported in Cereda, Klersy et. al. 2015</i> Nutritional intervention improved healing rates in both treatment and control groups. After 8 weeks, mean difference (experimental-control) in percentage reduction of at least 40% in wound size was 22.0% (95% CI 6.8 to 37.3, p=0.012) and 24.3% (95% CI 5.3 to 43.4, p=0.012) respectively. Economic analysis <ul style="list-style-type: none"> Usage of a high calorie, high protein ONS cost more money (mean difference in cost €39.40, 95% CI 31.60 to 47.10, p<0.001) When considering nutritional management and non-nutritional management (i.e. nursing and medical 	<ul style="list-style-type: none"> Analysis was only done on the direct cost of pressure injury care, indirect cost analysis not done- will require a more comprehensive economic view to assess the true cost Study was only conducted in one area in Italy. Cost of implementing this trial in other areas may vary. The endpoint of 8 weeks may be too short to see the true effect of a high caloric and protein supplement in the 	Level of evidence: N/A Quality: High

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics: <ul style="list-style-type: none"> • Mean age: 80.9-81.2 • BMI: 20.6- 21 • Braden Score: 11-11.9 • Location of PI: Sacral (42-44%), heel (9%), Trochanter (7-8%), Gluteus (3-4%), others (6%) 		focused on cost analysis. <ul style="list-style-type: none"> • Triple blindness was implemented. 	staff, dressing materials, antibiotics, support surfaces, medical tests) the cost of managing pressure injuries was cheaper (mean difference in cost – €74.30, 95% CI –126.1 to –22.5, p=0.013) <ul style="list-style-type: none"> • ≥95% of points were in the “more effective/less expensive” quadrant. <p>Author conclusions: A high caloric, high protein supplement with arginine, zinc and antioxidants can result in potential cost savings compared to isocaloric/isonitrogenous formulas when used for managing individuals with pressure injury.</p>	healing of pressure injury. <ul style="list-style-type: none"> • Conflict of interest has been mitigated for the study. 	
Hisashige & Ohura, 2012	RCT and economic analysis evaluating value for money of nutritional intervention for treating pressure injuries	Participants were recruited in long term care facilities in Japan (n=60) Inclusion criteria: <ul style="list-style-type: none"> • Tube fed • Category/stage 3 or 4 pressure injury • Albumin 2.5 to3.5 g/dL • Ohura-Hotta risk measurement scale 8.5 or lower • Braden scale 9 to 17 Participant characteristics: Mean age 80 to 81 years	<ul style="list-style-type: none"> • Participants were randomly assigned to received either: <ul style="list-style-type: none"> ○ Nutritional intervention with goal energy calculated using Basal energy expenditure x active factor (1.1) x stress factor (1.3 to 1.5), mean standard calories during the trial was 1,383.7±165.6kcal (n=30) ○ Standard nutrition, mean standard calories during trial was 1,092±161.8 kcal (n=30) 	<ul style="list-style-type: none"> • pressure ulcer days (PUDs) • quality-adjusted life years (QALYs) • Costs included nutritional interventions and local management of pressure injuries and were nutritional intervention, staff wages, dressing material, support surfaces, drugs, tests, all estimated from trial data • Outcomes reported at 12 weeks (after 12-week intervention) and 16 weeks (intervention plus 4 weeks observation) 	<p>Wound outcomes at 12 weeks</p> <ul style="list-style-type: none"> • Mean wound size was significantly smaller in the intervention group (0.7 versus 11.6 cm², p=0.019) • No significant difference in duration of days with pressure injury (p=0.462) <p>Cost comparison</p> <ul style="list-style-type: none"> • Mean cost per person was lower in the intervention group (\$3,718 versus \$4,603) • Incremental cost-effectiveness ratio (ICER) was –\$32,532 US for 12 weeks and a –\$38,726 US for 14 weeks • ICER showed most located in cost savings and greater effectiveness <p>Outcomes at 12 weeks</p> <ul style="list-style-type: none"> • Nutritional intervention reduced PUDs by 9.6 per person • QALYs increased by 0.226 x 10⁻² per person • Costs reduced by US \$542 per person 	<ul style="list-style-type: none"> • Based on very small RCT in Japan • Only considers direct costs 	Level of evidence: N/A Quality: High

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			<ul style="list-style-type: none"> Intervention continued for 12 weeks 		<p>Outcomes after 16 weeks</p> <ul style="list-style-type: none"> Nutritional intervention reduced PUDs by 16.2 per person QALYs increased by 0.382×10^{-2} per person Costs reduced by US \$881 per person 		
Tuffaha, Roberts, Chaboyer, Gordon, & Scuffham, 2015, 2016	Economic modelling to predict the cost of preventing pressure injuries associated with nutrition support	Sampling was from a systematic review that identified 5 RCTs comparing nutritional intervention to standard care for preventing pressure injuries	<ul style="list-style-type: none"> Standard care included regular pressure injury prevention such as support surfaces, repositioning, risk assessment, skin protection and standard hospital diet Intervention included patient education, patient monitoring of nutritional intake, nutrition goal setting, increasing intake by additional 1,000 to 2,000 kJ/day using 2-3 nutritional snacks or oral high protein supplements 	<ul style="list-style-type: none"> Time duration of studies varied from 2 weeks to 16 weeks 	<p>Pressure injury outcomes</p> <ul style="list-style-type: none"> Individual studies showed no effect for nutritional intervention Meta-analysis showed reduction in incidence of pressure injuries (relative risk 0.83, 95% CI 0.71 to 0.96, p=reported as significant) <p>Cost comparison</p> <ul style="list-style-type: none"> Estimated cost for nutritional support for 12 months was AUD \$33,687 versus AUD \$34,112 for standard nutrition Mean cost savings for nutritional intervention versus standard care was AUD \$425 per person QALY increased by an average of 0.005 <p>Author conclusions: model estimates that nutritional support is cost effective for preventing pressure injuries.</p>	<ul style="list-style-type: none"> Same report in two journals Interventions were varied across studies and included any nutritional intervention that increased energy intake Some data used to estimate expenses was over 20 years old 	<p>Level of evidence: N/A</p> <p>Quality: Moderate</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Miscellaneous nutrition-related evidence							
Roberts, Desbrow, & Chaboyer , 2016	RCT exploring feasibility of a program to improve oral intake in patients at risk of PU	<p>Participants were recruited in three medical wards in a university hospital in Australia (n=80 randomized, n=66 completed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Aged ≥ 18 years • Cognitively intact • At risk of PU based on restricted mobility • Expected length of stay ≥ 4 days • English literate <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Palliative care • Previous enrolment in study <p>Participant characteristics: (not significantly different between groups)</p> <ul style="list-style-type: none"> • Mean age approximately 7 years • Mean length of stay 16 to 28 days • Mean serum albumin 31-32g/L • Mean BMI 26 to 28 kg/m² 	<ul style="list-style-type: none"> • Participants were randomized to receive either: • nutritional program involving evidence-based education delivered verbally and in writing, self-monitoring of oral intake using a food chart, guided nutritional goal setting (n=39, n=2 not analyzed) or • Standard care consisting of nutritional screening, nutritional assessment and dietetic staff intervention if deemed appropriate (n=35, n=2 not analyzed) 	<ul style="list-style-type: none"> • Primary outcome measures focused on feasibility measures (agreement to participate, receiving intervention within 24 hours of randomization, retention rate) • Secondary outcome measure included improvement in energy and protein intake • Food intake collected for 3 days, self-completed by patients • Participant interviews 	<p>Feasibility</p> <ul style="list-style-type: none"> • Recruitment rate 81.6% • Retention rate 87.5% • 100% received at least some component of intervention • 38.7% completed diary independently for full 3 days and there was good correlation between these recordings and researcher observation of participant intake (r=0.965 to 0.993, p<0.001) <p>Intervention effect</p> <ul style="list-style-type: none"> • Intervention group had a significant increase in estimated energy requirements and estimated protein requirements over 3 days (p<0.05) • Control group had no significant change in estimated energy requirements and estimated protein requirements over 3 days <p>Author conclusions: a program decided to promote nutritional intake through patient engagement is effective in increasing energy and protein intake in patients at risk of PU</p>	<ul style="list-style-type: none"> • Participants who were required to fast for ≥ 2 meals were excluded from analysis • Intervention only tested in cognitively intact participants and English speakers • Small study that did not report PU as an outcome • Feasibility over longer time frame not tested 	Indirect evidence: PU not an outcome measure
Roberts, Desbrow, & Chaboyer , 2014 (J)	Qualitative study investigating patient perceptions of experiences with nutrition and	<p>Participants were recruited in two Australian hospitals with PU prevention programs (n=20)</p> <p>Inclusion criteria:</p>	N/A	<ul style="list-style-type: none"> • Purposive sampling technique • Interview questions focused on role of nutrition in PU prevention 	<p>Role of nutrition in PU prevention (5 themes)</p> <ul style="list-style-type: none"> • Recognizing the role of diet in PU prevention – participants had mixed level of understanding 	<ul style="list-style-type: none"> • Participants participated in an observational study on nutrition before interviews that may 	High quality qualitative study

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Wound Ostomy Continence Nurs)	dietitians during hospital admission	<ul style="list-style-type: none"> Aged ≥ 18 years Restricted mobility increasing risk of PU Length of stay ≥ 3 days <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean age 61.3±12.6 years Mean length of stay 7.4±13 days 		<p>and experiences with dietitians</p> <ul style="list-style-type: none"> Inductive content analysis conducted 	<ul style="list-style-type: none"> Promoting skin health with good nutrition – general a good understanding was displayed Understanding the relationship between nutrition and health Lacking insight into the role of nutrition in pressure injury prevention Acknowledging other risk factors– generally good understanding <p>Experiences with dietitians (2 themes)</p> <ul style="list-style-type: none"> Receptive of dietician input – appreciative and feeling lucky Displaying ambivalence towards dieticians’ advice – receiving conflicting advice, poor understanding of reasons, disempowering, did not like food, no new knowledge <p>Author conclusions: Patients have conflicting views and knowledge about dietary interventions and pressure injuries</p>	<p>have improved their knowledge</p> <ul style="list-style-type: none"> Selection of participants is not clear 	Indirect evidence: PU not an outcome measure
Dupuy et al., 2016	Cross sectional survey investigated practice of providing oral nutritional supplement (ONS) in aged care setting	<p>Participants were recruited in 175 nursing homes in France (n=6275 participants)</p> <p>Inclusion and exclusion criteria: Not reported in this paper</p> <p>Participant characteristics: Mean age 85 to 88 years</p>	<p>Survey asked if the individuals had a specific diet currently</p> <p>Survey collected demographic data on participants and facilities</p>	<ul style="list-style-type: none"> Prescription of ONS or otherwise 	<ul style="list-style-type: none"> 7.8% of participants received ONS More participants with a PU received ONS compared to those without a PU (13.3% vs 3.3%) Individuals with PU were significantly more likely to receive ONS than those 	<ul style="list-style-type: none"> Selection of participants is not reported in this paper (reported as being previously published) No data on whether receiving ONS was effective or 	Indirect evidence: PU not an outcome measure

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					<p>without a PU (Odds ratio 1.34, 95% C 1.06 to 1.70, p=0.001)</p> <ul style="list-style-type: none"> Other factors significantly associated with receiving ONS included low BMI (,21kg/m2). Weight loss in preceding month, disability in performing ADLs, pain and hospitalization in preceding year 	otherwise in promoting PU	
Gunnarsson, Lönn, & Gunningberg, 2009	Non-randomised pre/post-test investigating effectiveness of nutritional intervention on postoperative complications including PU	<p>n = 100 consecutive hip fracture patients at a Swedish orthopaedic ward</p> <p>Exclusion:</p> <ul style="list-style-type: none"> Dialysis or kidney disease requiring low protein diet or liquid restrictions Severe liver disease <p>Characteristics:</p> <ul style="list-style-type: none"> 71% female Mean age 81yrs Mean time before surgery was 24 hrs Intervention group had significantly (p=0.048) higher weight on admission Approximately 8% in each group had PU on admission Risk of PrU on Modified Norton Scale : control group 15.9 ± 3.5 (10-26); intervention group 16.6 ± 3.5 (10-24) p=0.398 	<p>Aim for all patients was to achieve 33% of daily need (30kcal/kg) on postop day 1, 50% of daily need on post op day 2 and 75% daily need by day 3.</p> <p>Where aim was not achieved, nasogastric feeding and glucose infusion for 12 hours.</p> <ul style="list-style-type: none"> Control group received (n=50 assigned, 23 did not participate): <ul style="list-style-type: none"> Glucose infusion preoperatively (1,00ml, 50mg/ml) Standard hospital diet postoperatively Intervention group received (n=50 assigned, 35 did not participate): <ul style="list-style-type: none"> Glucose infusion (3,00ml, 50mg/ml) and carbohydrate drink (800ml) pre operatively Drinking supplement (520 ml) and standard 	<p>All data collected daily for one pre-operative period and five days postoperatively:</p> <ul style="list-style-type: none"> Risk of PU on Modified Norton Scale (MNS) with score ≤ considered at risk Presence of PU based on EPUAP classification Weight Nosocomial infections Cognitive ability (short portable mental status questionnaire) Walking assistance Functional ability on Katz index 	<ul style="list-style-type: none"> Significantly fewer (p=0.043) patients in the intervention group n=9 (18%) had PUs five days postoperatively compared with the control group n=18 (36%) Incidence of newly occurring PU was lower in intervention group (18% versus 28%) Nutrient and liquid intake (compliance with intervention) was significantly higher (p < 0.001) in the intervention group Median length of stay was significantly less in intervention group (7 days versus 9 days, p=0.137) Nosocomial infections significantly decreased (18 % versus 8.7% , p=0.137) Predictors of developing PU: <ul style="list-style-type: none"> PU on admission OR=30.55, 95% CI 2.8 to 338.6, p<0.005 Nutritional intervention OR=0.31, 95% CI 0.1 to 1.0, p=0.049 Preoperative length of stay OR=2.41, 95% CI 1.3 to 4.4, p=0.004 	<ul style="list-style-type: none"> No randomization High level of non-participation Short study period 	<p>Level of evidence: 4</p> <p>Quality: Moderate</p>

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			hospital diet postoperatively		Conclusions: regular skin inspection, assessment of PU risk and early nutritional supplementation may contribute to a reduced incidence of PU in elderly hip fracture patients		
Morello et al., 2009	5-year epidemiological analysis investigating demographics of patients receiving enteral nutrition (EN) in nursing homes	n=482 nursing home residents in Italy recruited 2001 to 2005 Characteristics: <ul style="list-style-type: none"> • Mean age 81±13 yrs • Primarily females over 76 yrs • Mean weight 54.1±12 kgs • Mean BMI 20.7±3.9 kg/m² • 42.3% had PUs 	<ul style="list-style-type: none"> • Data was collected at the initiation of EN including: <ul style="list-style-type: none"> ○ age and gender ○ underlying disease ○ Karnofsky index ○ type of enteral access device ○ presence of PUs ○ weight and BMI ○ daily enteral intake 	<ul style="list-style-type: none"> • Patient survival • Duration of therapy 	<ul style="list-style-type: none"> • An average of 6.6% nursing home residents received EN • Almost all participants receiving EN had a Karnofsky index ≤ 50 • Median duration of EN was 296 days and median survival was 411 days • Direct relationship observed between severity of PU and age p<0.01 at baseline. <p>Conclusions: 42.3% of older adults commenced on enteral nutrition had a pre-existing PU that was significantly more likely (p<0.01) to be more severe as age increased.</p>	<ul style="list-style-type: none"> • Clinical monitoring is not analyzed • PU status not an outcome measure. • Does not state how PU presence and severity was assessed 	Indirect evidence (not specific to pressure injuries)
Shinji Iizaka, Okuwa, Sugama, & Sanada, 2010	Prognostic case-control study investigating relationship between nutritional status and PU development	Random selection of 537 home care offices in Japan for identification of participants. Final inclusion was n=746 (290 participants with home-acquired PUs and 456 without PUs) Inclusion: <ul style="list-style-type: none"> • ≥65 yrs of age • Either no history of PU if in non-PU group, or history of at least one home-acquired PU if in PU group Exclusion:	Records analysis for collection of data on PU Questionnaire addressing 21 key factors associated with incidence of PU was completed by the primary nurse (with or without participant present). Questionnaire included mobility, contracture, oedema, skin moisture, continence, care levels, nutritional status, methods for nutritional assessments, use of dietitian	Presence of home-acquired PU status collected via records analysis Secondary outcome was depth (partial or full thickness) of the PU collected via records analysis	<ul style="list-style-type: none"> • Of those with a PU, 157 (54.1%) had superficial PUs and the remainder (45.9%) had a full-thickness PU <p>Groups comparison of nutrition and PUs</p> <ul style="list-style-type: none"> • Malnutrition was higher in participants with a PU (58.7% versus 32.6%, p<0.001) • Those with a PU were less likely to have a nutritional intervention (1.3% versus 7.5%, p<0.001) • Caregiver for those without PU had stronger knowledge about 	<ul style="list-style-type: none"> • Only 40% of care facilities participated in the survey • Results relied on response from primary nurse • Some data about nutritional management is missing • Multivariate analyses could not be conducted due to multicollinearity 	Level of evidence: 3 Quality: Moderate

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> Unknown age, gender or care status PU status undocumented (e.g. location, depth) <p>Characteristics:</p> <ul style="list-style-type: none"> Mean age 82 to 84 years Approx. 59% female >80% required highest level of care Group with PU less likely to have cerebrovascular disease (34% versus 47%, p=0.001) and type I diabetes (12.1% versus 17.5%, p=0.044) than those without PU 			<p>nutrition (41.7% versus 23.3%, p<0.001)</p> <ul style="list-style-type: none"> Participant's with PUs had caregivers who less frequently conducted nutritional assessment (90.7% versus 76.9%, p<0.001) <p>Factors associated with PU presence</p> <ul style="list-style-type: none"> Malnutrition was significantly associated with higher rate of PU after adjusting for other risk factors (OR=2.29; 95% CI, 1.53 to 3.44). Malnutrition was most significant factor above immobility, level of care needed and presence of contractures. Malnutrition was significantly associated with more severe (full thickness) PUs (OR 1.88, 95% CI 1.03 to 3.45) Assessment by a health professional of nutritional status (OR=0.43 95% CI 0.27 to 0.68) and of the dietary intake (OR=0.43, 0.47, 95% CI 0.28 to 0.79) were associated with lower odds for developing PUs <p>Conclusions: For older adults in home care, malnutrition is associated with both presence of PUs and with PU severity. Assessment of dietary status is important in preventing PUs.</p>		
M. Banks, Bauer,	Cross-sectional study investigating the effect of	Participants were recruited from 20 acute care hospitals (n=2208) and 6 residential aged	Nutritionists assessed nutritional status in a separate data collection.	<ul style="list-style-type: none"> Subjective Global Assessment 	<ul style="list-style-type: none"> Participants in acute care with malnutrition had adjusted odds 	<ul style="list-style-type: none"> Cross-sectional rather than longitudinal design 	Level of evidence: 4

Nutrition: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Quality:
Graves, & Ash, 2010	nutritional status on presence and severity of PU	<p>care facilities (n=839) in Australia in 2002 and in 2003.</p> <p>Characteristics:</p> <ul style="list-style-type: none"> Acute care in 2002: average age 66.5±7.8 years, 48.4% sample female Acute care in 2003: average age 66.0±18.8 years, 46.2% sample female Aged care in 2002: average age 78.9±12.5 years, 61.2% sample female Aged care in 2003: average age 78.7±12.4 years, 65.5% sample female 	Other data collected by auditors (primarily nurses) on a single day in each facility.	<ul style="list-style-type: none"> PU stage according to the AWMA staging system 	<p>ratio of having PU of 2.6 (95% CI 1.8 to 3.5, p<0.001)</p> <ul style="list-style-type: none"> Participants in aged care with malnutrition had adjusted odds ratio of having PU of 2.0 (95% CI 1.5 to 2.7, p<0.001) When severity of malnutrition increased there was an increased OR for having a PU and more likelihood of a more severe PU. Conclusions: there was at least twice the odds ratio of having a PU in public health facilities for people with malnutrition. 	<ul style="list-style-type: none"> Study does not account for comorbidities 	Moderate

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Nutrition: data extraction and appraisals

Additional evidence from systematic reviews to support discussion

Ref	Type of Study	Types of studies	Types of interventions	Outcome measures	Results	Limitations and comments	
E. Cereda, Neyens, Caccialanza, Rondanelli, & Schols, 2017	Systematic review reporting RCTs on the efficacy of high-calorie, high-protein nutritional formula enriched with arginine, zinc, and antioxidants (disease-specific support) for people with PUs	<p>Systematic review on disease-specific nutritional supplements for people with PU</p> <p>Limited to publications 1997 to 2015 with an intervention period of at least 4 weeks</p> <p>Included three studies in meta-analysis, all included in Guideline</p> <p>Participants in two studies were diagnosed as having malnutrition All studies set in long term care facilities Studies of duration 8 to 12 weeks</p>	<ul style="list-style-type: none"> Nutritional supplements were oral with or without tube supplements One study did not report the content of the nutritional supplement <p>Two studies reported contents to be equivalent to 27 to 30 kcal/kg/day, 1.5 g/kg/day</p>	<ul style="list-style-type: none"> Reduction in wound area ≥40% reduction in PU size at 8 weeks Complete healing at 8 weeks Percentage of change in the area at 4 weeks 	<p>Reduction in wound area Disease specific nutritional supplement was associated with a significantly greater reduction in wound area (mean difference -15.7% (95% CI -29.9 to -1.5, p=0.030, I²=58.6%)</p> <p>≥40% reduction in PU at week 8 Disease specific nutritional supplement was associated with a significantly more PUs achieving ≥40% reduction (OR=1.72, 95% CI 1.04 to 2.84, p=0.033, I²=0.0%)</p> <p>Complete healing at 8 weeks There was no significant difference between disease specific nutritional supplement and control diets in PUs achieving complete healing at 8 weeks (OR=1.72, 95% CI 0.86 to 3.45. p=0.127; I²=0.0%)</p> <p>Percentage of change in the area at 4 weeks There was no significant difference between disease specific nutritional supplement and control diets in percent change in PU at 4 weeks (-7.1%, 95% CI -17.4 to 3.3, p=0.180, I²=0.0%)</p>	<ul style="list-style-type: none"> Reviewers were authors of 2/3 included papers, does not discuss how conflict was managed All studies are included in Guideline 	Quality: Moderate
Avenell, Smith, Curtain, Mak, & Myint, 2016	Systematic review reporting RCTs on nutrition supplement for older adults post hip surgery	<p>Systematic review on nutritional supplements for older adults following hip fracture (aged > 65 years with hip fracture and eligible for surgery)</p> <p>Only two studies reporting pressure injury as an outcome measure were identified, one of which is already</p>	<ul style="list-style-type: none"> Participants received either: <ul style="list-style-type: none"> Oral Restorfast supplement containing 345 mg L-carnitine, 500 mg calcium, 250 mg magnesium, 5 mcg vitamin D3, 500 mg L-leucine taken for 6 weeks followed by Riabylex daily (1500 mg) 	Complications	<p>Hospital acquired PUs There was no benefit of supplementation on hospital acquired PUs (3/38 versus 6/41; RR0.54, 99% CI 0.10 to 3.03)</p>	<ul style="list-style-type: none"> 50% dropout rate Italian study translated for the Cochrane review Method of measuring PU not reported 	Quality: High

Nutrition: data extraction and appraisals

		<p>reported in the international guideline</p> <p>One additional study was a low quality RCT conducted in Italy (n=107 participants, n=52 completed)</p>	<ul style="list-style-type: none"> ○ creatine, 250 mg L-carnitine, 20 mg coenzyme Q10, nicotinamide 18 mg, pantothenic ○ acid 6 mg, riboflavin 1.6 mg) for a further 10 weeks, or ○ No intervention 			<ul style="list-style-type: none"> • Reports only one RCT not included in guideline 	
Langer & Fink, 2014	<p>Cochrane review on nutritional interventions for prevention and treatment of PU</p>	<p>Systematic review included 23 RCTs</p> <p>15 RCTs in hospital, 2 in a range of settings, 3 in long term care Studies primarily from Europe</p> <p>Mostly small sample sizes (median size n=88)</p> <p>All RCTs had some level of bias, most did not achieve at least half of the quality indicators</p>	<ul style="list-style-type: none"> • 11 RCTs trialed mixed nutritional supplements to prevent PU (e.g. energy rich, protein only, mixed protein/vitamin/carbohydrate) • 6 RCTs trialed nutritional supplement to treat PU • 3 RCTs considered enteral nutrition or supplement 	<ul style="list-style-type: none"> • Prevention of PU • PU size, healing on PUSH score, PU appearance, PU volume • Adverse events of supplements 	<p>PU prevention (11 trials)</p> <ul style="list-style-type: none"> • 10/11 trials at high or unclear risk of bias showed the nutritional supplement was superior to a standard diet for preventing PU • Compared to standard diet, there was a significant association between a nutritional supplements and prevention of PUs (8 pooled RCTs, risk ratio [RR] 0.86, 95% CI 0.73 to 1.00, p=0.05) • Two RCTs that compared different nutritional supplements found no significant difference between the two interventions <p>PU treatment (11 trials)</p> <ul style="list-style-type: none"> • Compared to standard diet, arginine rich supplements were superior in achieving significant improvements in PUSH score (3 RCTs, mean difference -3.18, 95% CI -4.00 to -1.56, p=0.0001) • Compared to standard diet, arginine rich supplements were not significantly different for achieving significant reduction in PU size (2 RCTs, mean difference -4.20, 95% CI -9.80 to -1.40, p=0.14) <p>Author conclusions: The evidence is not clear on whether nutritional interventions reduce PUs or promote healing</p>	<ul style="list-style-type: none"> • Evidence is from studies at high or unclear risk of bias 	Quality: High

Nutrition: data extraction and appraisals

<p>Cereda, E., Klersy, C., Rondanelli, M., & Caccialanza, R. (2011).</p>	<p>Systematic review and meta-analysis of observational studies reviewing individualized energy intake requirements for individuals with a pressure injury</p>	<p>Five studies were included in the meta-analysis; n = 193 (Control = 101; patient with PUs = 92)</p>	<ul style="list-style-type: none"> • Searches for all language, original, full text research articles that were published between January 1, 1950 and July 31, 2010 were carried out within electronic databases • Key words: decubitus ulcer; pressure sore and pressure ulcer coupled with resting metabolic rate, resting energy expenditure, basal metabolic rate and indirect calorimetry 	<ul style="list-style-type: none"> • Observational (case control and case series) studies providing data on measured resting energy expenditure (REE) were initially included • Data extracted were: <ul style="list-style-type: none"> ○ Measured REE ○ Predicted REE ○ Daily energy intake 	<ul style="list-style-type: none"> • Patients with pressure injuries presented higher measured REE (weighted mean 20.7 ± 0.8 vs. 23.7 ± 2.2 kcal/kg/day $P < 0.0001$) • In patients measured REE was also higher than predicted REE • Energy intake was significantly lower ($P < 0.0001$) than total daily requirement which was calculated as 29.4 ± 2.7 kcal/kg/day • Patients with PrUs are characterized by increased REE and reduced energy intake • An energy intake of 30 kcal/kg/day seems appropriate to cover the daily requirements of patients with pressure injuries 	<ul style="list-style-type: none"> • Number of studies and small size of PU and control groups • Heterogeneity of study samples and lack of information on potential confounding factors 	<p>Quality: High</p>
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Table 1: Level of Evidence for Intervention Studies

Level 1	Experimental Designs <ul style="list-style-type: none"> • Randomized trial
Level 2	Quasi-experimental design <ul style="list-style-type: none"> • Prospectively controlled study design • Pre-test post-test or historic/retrospective control group study
Level 3	Observational-analytical designs <ul style="list-style-type: none"> • Cohort study with or without control group • Case-controlled study
Level 4	Observational-descriptive studies (no control) <ul style="list-style-type: none"> • Observational study with no control group • Cross-sectional study • Case series (n=10+)
Level 5	Indirect evidence: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models

Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.
Level 2	Non-consecutive studies or studies without consistently applied reference standards.
Level 3	Case-control studies or poor or non-independent reference standard.
Level 4	Mechanism-based reasoning, study of diagnostic yield (no reference standard). Low and moderate quality cross sectional studies.

Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	A prospective cohort study.
Level 2	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
Level 3	Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.

APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS)

Each criteria on the critical appraisal forms was assessed as being fully met (Y), partially met or uncertain (U), not met/not reported/unclear (N), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria

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CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

Endnote ID	Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Level of evidence	Quality
8051	Tsaousi et al., 2015	Y	Y	Y	Y	U	N	NA	Y	Y	U	4	moderate
1741	Monteferrario et al., 2013	N	U	N	Y	U	Y	NA	Y	U	U	4	low
17143	Kennerly et al., 2015	Y	Y	U	Y	U	Y	Y	N	Y	U	4	moderate
7503	Corrales et al., 2014	N	Y	U	N	Y	Y	NA	N	Y	U	4	low

PROGNOSTIC STUDIES

Author/year	Adequate description of baseline characteristics	Satisfactory study attrition	Clear outcome measures/prognostic factors	Range of prognostic factors/confounders measured identified and	Method of measuring prognostic factor is reported, valid and reliable	Same method of measure of prognostic factor for all	Continuous variables or appropriate cut offs	Percent participants with complete data acceptable	Appropriate imputation method	Confounders/prognostic factors accounted for in analysis	Selective reporting avoided	Adequate sample size (10 PIs per factor)	Level of evidence	Quality
13970	Grattagliano et al., 2017	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	1	high
1429	Yatabe et al., 2013	N	Y	Y	N	Y	Y	U	U	Y	Y	N	3	Low

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RCTS

Endnote ID	Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measure	% drop out in study arms is reported and acceptable	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
17148	Houwing et al., 2003	Y	Y	U	Y	Y	Y	Y	Y	Y	U	Y	Y	1	High
17140	Delmi et al., 1990	Y	N	N	U	Y	U	U	Y	Y	NA	N	N	1	Low
17146	Ek et al., 1991	Y	U	U	U	N	N	Y	U	Y	NA	Y	N	1	Low
1879	Ohura et al., 2013	Y	N	N	N	Y	Y	Y	Y	Y	U	U	Y	1	Low
17138	I. Bourdel-Marchasson et al., 2000	Y	N	N	N	N	N	Y	Y	Y	U	U	Y	1	Low
17132	Desneves et al., 2005	U	Y	U	Y	N	U	Y	Y	Y	NA	Y	Y	1	Moderate
17135	Benati et al., 2001	Y	U	N	U	U	U	Y	Y	Y	NA	U	U	1	Low
13368	M. D. Banks et al., 2016	Y	U	N	N	Y	Y	Y	N	N	NA	Y	Y	1	Low
7866	Wong et al., 2014	Y	U	Y	Y	Y	Y	Y	Y	N	NA	N	N	1	Moderate
13921	Yamanaka et al., 2017	Y	Y	Y	U	Y	Y	Y	N	N	U	Y	Y	1	low
10970	Harvey et al., 2016	Y	Y	Y	N	Y	Y	U	Y	Y	Y	Y	Y	1	high
8007	E. Cereda et al., 2015	Y	Y	Y	Y	Y	Y	Y	N	Y	U	Y	Y	1	high

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QUASI EXPERIMENTAL STUDIES

	Author/year	Focused question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported and	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
51	Sakae, Agata, Kamide, & Yanagisawa, 2013	Y	U	Y	Y	Y	N	Y	NA	U	U	2	low
17141	Breslow et al., 1991	Y	N	N	Y	Y	Y	Y	NA	Y	Y	2	moderate

COHORT STUDIES

	Author/year	Focused question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
6750	Amano et al., 2013	Y	Y	Y	N	NA	NA	Y	Y	Y	N	N	Y	N	Y	3	low
3014	S. Iizaka et al., 2014	Y	Y	N	Y	Y	N	Y	N	Y	Y	U	N	U	U	3	low
17131	Heyman et al., 2008	Y	N	N	N	U	U	Y	Y	Y	Y	N	N	U	U	3	low
6115	Li, Kato, Matsuoka, Tanaka, & Miwa, 2013	Y	Y	N	N	NA	NA	Y	U	Y	U	N	N	U	U	3	low
17134	Frias Soriano et al., 2004	Y	N	N	N	N	N	Y	N	Y	U	U	N	U	U	3	low
17142	Breslow et al., 1993	Y	NA	Y	NA	N	NA	Y	Y	N	N	U	N	N	N	3	low
10913	Meehan et al., 2016	Y	U	Y	U	NA	NA	Y	U	U	U	Y	N	U	U	3	low

ECONOMIC EVALUATIONS

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	Author/year	Focused question	Economic importance of question is clear	Choice of study design is justified	All costs are included and measured and valued appropriately	Outcome measures to answer study question are relevant and measured and valued appropriately	Discounting of future costs and outcome measures is performed correctly when appropriate	Assumptions explicit and a sensitivity analysis conducted	Results provide information relevant for policy providers	Minimal bias	Reliable conclusions	Level of evidence	Quality
14649	E. Cereda, Klersy, et al., 2017	Y	Y	Y	Y	Y	NA	Y	Y	Y	Y	NA	High
5954	M. D. Banks et al., 2013	Y	Y	Y	U	U	NA	N	Y	Y	Y	NA	Moderate
17130	Hisashige & Ohura, 2012	Y	Y	Y	Y	Y	NA	Y	Y	Y	Y	NA	High
16423 6693	Tuffaha et al., 2015, 2016	Y	Y	U	U	N	NA	N	Y	U	Y	NA	Moderate

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SYSTEMATIC REVIEWS FOR DISCUSSION

RATING CRITERIA:

- 1 Partial yes: states review question, search strategy, in/exclusion criteria and risk of bias were a-priori; full yes: meta-analysis/synthesis plan, investigation of heterogeneity and justification for protocol deviation
- 2 Partial yes: At least 2 databases, provides keywords and search, justifies publication restrictions; full yes: searched reference lists of included studies, searched trial registries, consulted experts in field, searched grey literature, search within 24 months of review completion
- 3 At least two reviewers independently agreed on selection of studies to include or reviewers achieved 80% agreement on a sample of studies
- 4 Either two reviewers did data extraction and had >80% agreement, or two reviewers reached consensus on data to extract
- 5 Partial yes: list of all relevant studies that were read and excluded; full yes: every study that was excluded is independently justified
- 6 Partial yes: described populations, interventions, comparators, outcomes and research design; full yes: detailed descriptions of same plus study setting and timeframe for follow-up
- 7 FOR RCTS Partial yes: appraised risk of bias from unconcealed allocation and lack of blinding; full yes: appraised risk of bias on true randomisation, selection of reported result from multiple measurements/analyses
- FOR non randomised studies: Partial yes: appraised confounding and selection bias; full yes: appraised methods to ascertain exposures and outcomes, selection of reported result from multiple measurements/analyses
- 8 Must include reporting of the source of funding of individual studies, or reports that the reviewers considered this even if individual funding sources aren't listed in review

Endnote ID	Author/year	PICO research question and inclusion criteria	Explicitly states a-priori protocol ¹	Rationale for selection of study designs	Comprehensive search ²	Duplicate study selection ³	Duplicate data extraction ⁴	Excluded studies listed ⁵	Adequate description of included studies ⁶	Risk of bias assessed ⁷	Source of funding reported ⁸	Appropriate meta-analysis including weighting and adjustment for heterogeneity	Meta-analysis considers risk of bias of studies	Discussion consider risk of bias of studies	Assessment of publication bias if quantitative analysis is done	Potential conflicts of interest of authors reported and managed	Review Inclusion/Exclusion
13676	Avenell et al., 2016	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	Include
7836	Langer & Fink, 2014	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	Include
14026	E. Cereda, Neyens, et al., 2017	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Include
9559	Ribeiro Salomon & Carvalho Garbi Novaes, 2015				Y			Y		Y		NA		N	NA		Exclude
16107	Wong, Goh, Banks, & Bauer, 2017				Y			N		Y		NA		Y	NA		Exclude

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Endnote ID	Author/year	PICO research question and inclusion criteria	Explicitly states a-priori protocol ¹	Rationale for selection of study designs	Comprehensive search ²	Duplicate study selection ³	Duplicate data extraction ⁴	Excluded studies listed ⁵	Adequate description of included studies ⁶	Risk of bias assessed ⁷	Source of funding reported ⁸	Appropriate meta-analysis including weighting and adjustment for heterogeneity	Meta-analysis considers risk of bias of studies	Discussion consider risk of bias of studies	Assessment of publication bias if quantitative analysis is done	Potential conflicts of interest of authors reported and managed	Review Inclusion/Exclusion
14519	Heintschel & Heuberger, 2017				N			N		N		NA		N	NA		Exclude
14434	Liu, Shen, & Chen, 2017				Y			N		Y		NA		N	NA		Exclude
9009	Blanc et al., 2015				Y			N		Y		NA		N	NA		Exclude
12846	Agarwal, Marshall, Miller, & Isenring, 2016				Y			N		N		NA		N	N		Exclude

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