CUBITAN EVIDENCE BOOKLET

AN OVERVIEW OF CUBITAN'S CLINICAL EVIDENCE IN THE DIETARY MANAGEMENT OF WOUNDS

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Contents

INTRODUCTION

Pressure ulcers (PUs) are a major and often understated public health problem across the world[1]. Within Ireland it has been estimated that the prevalence of pressure ulcers within the acute setting ranges between 12-19%[2]. Furthermore, within the long term care settings, it has been estimated up to 25% of patients develop pressure ulcers[3]. This is an important healthcare issue associated with a substantial economic burden. Previous estimations include a €119,000 cost of treatment for one patient with a grade 4 pressure ulcer in Ireland and an overall cost of €250 million per annum to manage pressure ulcers in Ireland[4].

Previously the benefit associated with nutritional interventions for the treatment of pressure ulcers was limited to methodology and heterogeneity in the study designs, in recent years different studies have provided supporting evidence of a role of nutritional interventions in pressure ulcer healing with more recently a large high quality randomised control trial[5].

In addition, the newly released international guideline mentions to provide adequate protein for positive nitrogen balance for an individual with a pressure ulcer. (Strength of Evidence = B) and to provide 30-35 kcalories/kg body weight for individuals under stress with a pressure ulcer. (Strength of Evidence = C)[1]

The most important micronutrients studied include[6,7]:

Arginine. This is a semi-essential amino acid that contributes to protein synthesis, including the deposition of collagen. It is a precursor of nitrogenous bases and acts as an antioxidant. Arginine is also necessary for the synthesis of nitric oxide, a molecule that is toxic to bacteria and acts as a vasodilator. Finally, it is a mediator of immune response and stimulates the secretion of growth hormones, making it a powerful anabolic agent.

Zinc. Zinc is a mineral required for catalysing at least 100 enzymes, including metalloproteinases (involved in remodelling the connective tissue). It also performs an important role in the immune system, DNA synthesis, gene expression, protein synthesis (including collagen) and cell proliferation.

Vitamin C. Vitamin C performs an essential role in the synthesis of collagen in the connective tissue, helping to form the bonds that stabilise the formation of fibrillar collagen. It is a potent antioxidant and is important for the proliferation of fibroblasts and the cytotoxic activity of the leukocytes.

Vitamin E. The primary function of this substance is as an antioxidant.

Copper. Copper is an important cofactor of mitochondrial cytochrome c-oxidase (involved in the energy metabolism of all cells) and cytoplasmic superoxide-dismutase (an enzyme with potent antioxidant activity); the mineral is also needed for the correct functioning of lysyl oxidase, an enzyme that favours the formation of bonds allowing collagen fibres to develop.

Selenium. Selenium is an essential mineral for the human body. It is the cofactor of glutathione peroxidase, an enzyme family that primarily performs antioxidant activity within the biological systems.

TREATMENT STUDIES

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TREATMENT STUDIES

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Cereda E., Klersy C., Serioli M., Crespi A., D'Andrea F. for OEST Study Group.

A Nutritional Formula Enriched with Arginine, Zinc and Antioxidants for the Healing of Pressure Ulcers: A Randomized, Controlled Trial.

The Oligoelement Sore Trial (OEST).
Annals of Internal Medicine, 2015; 162:167-174.

Background: Trials on specific nutritional supplements for the treatment of pressure ulcers (PUs) have been small, inconsistent in their formulations, or unsuccessful in controlling for total supplement calorie or protein content.

Objective: To evaluate whether supplementation with arginine, zinc, and antioxidants within a high-calorie, high-protein formula improves PU healing.

Design: Multicenter, randomized, controlled, blinded trial.

Setting: Long-term care and home care services.

Patients: 200 adult malnourished patients with stage II, III, and IV PUs.

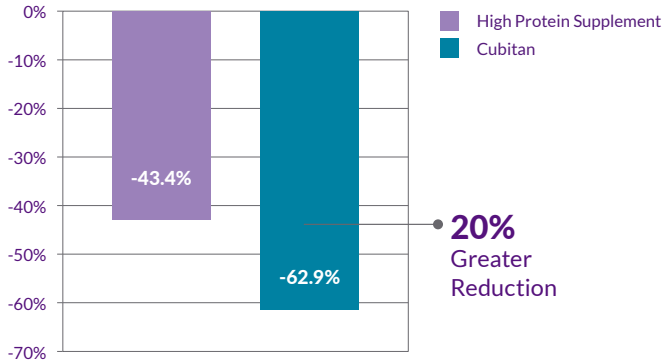
Interventions: An energy-dense, protein-rich oral formula enriched with arginine, zinc, and antioxidants (400 mL/d) or an equal volume of an isocaloric, isonitrogenous formula for 8 weeks.

Measurements: The primary end point was the percentage of change in PU area at 8 weeks. Secondary end points included complete healing, reduction in the PU area of 40% or greater, incidence of wound infections, the total number of dressings at 8 weeks, and the percentage of change in area at 4 weeks

Results: Supplementation with the enriched formula (n=101) resulted in greater reduction in PU area (mean reduction 60.9% [95% CI, 54.3% - 67.5%]) than with the control formula (n=99) (45.2% [CI, 38.4% - 52.0%]) (adjusted mean difference, 18.7% [CI, 5.7% - 31.8%]; P=0.017). A more frequent reduction in area of 40% or greater at 8 weeks was also seen (odd ratio, 1.98 [CI, 1.12 - 3.48]; p=0.0180. No difference was found in terms of the other secondary end points.

Conclusion: Among malnourished patients with PU, 8 weeks of supplementation with an oral energy-dense formula enriched with arginine, zinc and antioxidants improved pressure ulcer healing.

Treatment with Cubitan® for 8 weeks was found to be cost-effective and required a lower number of dressings p = 0.005. Mean difference (95% CI) between the experimental and control formula groups.



Van Anholt R.D., Sobotka L, Meijer E.P., Heyman H., Groen H.W., Topinková E., van Leen M., Schols J.M.G.A.

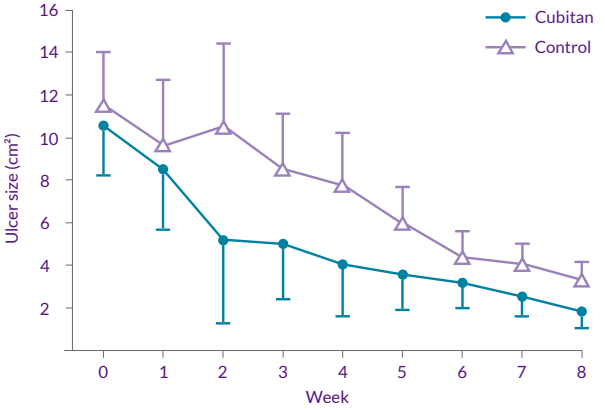
Specific nutritional support accelerates pressure ulcer healing and reduces wound care intensity in non-malnourished patients.

Nutrition, 2010. 26(9): p. 872-72.

Objective: An investigation into the potential of a high-protein, arginine- and micronutrient-enriched oral nutritional supplement (ONS) to improve healing of pressure ulcers in non-malnourished patients who would usually not be considered for extra nutritional support.

Methods: Forty-three non-malnourished subjects with Stage III or IV pressure ulcers were included in a multicountry, randomized, controlled, double-blind, parallel group trial. They were offered 200mL of the specific ONS or a non-caloric control product three times per day, in addition to their regular diet and standard wound care, for a maximum of 8 wk. Results were compared with repeated-measures mixed models (RMMM), analysis of variance, or Fisher's exact tests for categorical parameters.

Results: Supplementation with the specific ONS accelerated pressure ulcer healing, indicated by a significantly different decrease in ulcer size compared with the control, over the period of 8 wk (P≤ 0.016, RMMM). The decrease in severity score (Pressure Ulcer Scale for Healing) in the supplemented group differed significantly (P ≤0.033, RMMM) from the control. Moreover, significantly fewer dressings were required per week in the ONS group compared with the control (P ≤0.045, RMMM) and less time was spent per week on changing the dressings (P≤ 0.022, RMMM). At the end of the study, blood vitamin C levels had significantly increased in the ONS group compared with the control (P= 0.015, analysis of variance).



Mean pressure ulcer size (cm^2) in time in the group receiving specific ONS and in the control group. Ulcers if patients in the ONS group healed significantly faster than those of patients in the control group (P=0.006, treatment by time; P=0.016, treatment by $time^2$ repeated-measures mixed models). Data adjusted for centre, represent mean ±SEM (Standard error of mean).

Conclusion: Specific nutritional supplementation accelerated healing of pressure ulcers and decreased wound care intensity in non-malnourished patients, which is likely to decrease overall costs of pressure ulcer treatment.

Cereda, E., Gini, A., Pedrolli, C., Vanotti, A.

Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalized older adults: A randomized controlled trial.

J Am Geriatr Soc, 2009. 57: p. 1395-1402.

Objective: To investigate whether a disease-specific nutritional approach is more beneficial than a standard dietary approach to the healing of pressure ulcers (PUs) in institutionalized elderly patients.

Design: Twelve-week follow-up randomized controlled trial (RCT).

Setting: Four long-term care facilities in the province of Como, Italy.

Participants: Twenty-eight elderly subjects with grade II, III, and IV PUs of recent onset (<1 month history).

Intervention: All 28 patients received 30 kcal/kg per day nutritional support; of these, 15 received standard nutrition (hospital diet or standard enteral formula; 16% calories from protein), whereas 13 were administered a disease-specific nutrition treatment consisting of the standard diet plus a 400ml oral supplement or specific enteral formula enriched with protein (20% of the total calories), arginine, zinc, and vitamin C (P<.001 for all nutrients vs control).

Measurements: Ulcer healing was evaluated using the Pressure Ulcer Scale for Healing (PUSH; 0=complete healing, 17=greatest severity) tool and area measurement (mm^2 and %).

Results: The sampled groups were well matched for age, sex, nutritional status, oral intake, type of feeding, and ulcer severity. After 12 weeks, both groups showed significant improvement (P<.001). The treatment produced a higher rate of healing, the PUSH score revealing a significant difference at Week 12 (-6.1+/-2.7 vs -3.3+/-2.4; P<.05) and the reduction in ulcer surface area significantly higher in the treated patients already by Week 8 (-1,140.9+/-669.2 mm^2 vs -571.7+/-391.3 mm^2; P<.05 and ~57% vs ~33%; P<.02).

Conclusion: The rate of PU healing appears to accelerate when a nutrition formula enriched with protein, arginine, zinc, and vitamin C is administered, making such a formula preferable to a standardized one, but the present data require further confirmation by high-quality RCTs conducted on a larger scale.

Heyman, H., Van De Looverbosch, D.E., Meijer E.P., Schols J.M.G.A.

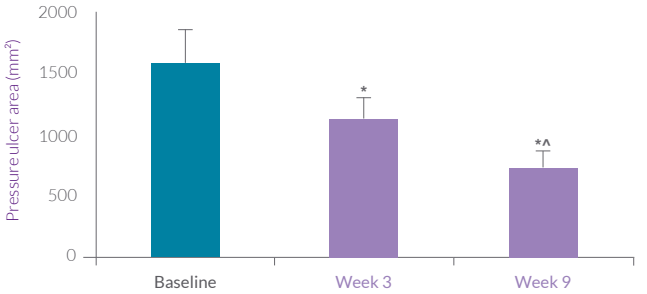
Benefits of an oral nutritional supplement on pressure ulcer healing in long-term care residents.

J Wound Care, 2008. 17(11): p. 476-480.

Objective: To investigate the effects of an ONS plus standard care on the healing of pressure ulcers in long-term nursing home residents in addition to standard care. The ONS (Cubitan, Nutricia Advanced Medical Nutrition) was high in energy and protein, and enriched with arginine, vitamin C and zinc.

Method: A total of 245 patients with grade II-IV pressure ulcers were enrolled into this open study at 61 long-term care facilities, which reflect the nursing home population of Luxembourg and Belgium. Residents received the ONS daily for nine weeks, along with their normal diet or enteral feed and standard pressure care. Pressure ulcer area (mm^2) and condition were assessed after three and nine weeks. Data were analysed using ANOVA and expressed as mean ± SD.

Results: The patients' age was 82.2 ± 10.1 years. Sixty-seven patients (27%) had been previously treated with the ONS. The majority of pressure ulcers were located at the sacrum (54%) and heel (32%). The average intake of the 200ml ONS was 2.3 ± 0.56 servings daily, which corresponds to 46g protein, 6.9g arginine, 575mg vitamin C, 87mg vitamin E and 21mg zinc. After nine weeks nutritional support, the average pressure ulcer area reduced significantly from 1580 ± 3743mm^2 to 743 ± 1809mm^2, which is a reduction of 53% ($p<0.0001$). Complete wound closure occurred after three and nine weeks in 7% and 20% of the pressure ulcers respectively. The amount of exudation (assessed subjectively) also decreased after specialised nutritional support ($p<0.0001$).



Mean data ± SE
*P<0.0001 compared with baseline; ^ p<0.0001 compared with week 3, visit 2.

Conclusion: A high-protein ONS enriched with arginine, vitamin C, vitamin E and zinc, when used with standard pressure ulcer care, significantly reduced the mean pressure ulcer area of long-term nursing home residents.

Frias Soriano, L., Lage Vázquez, M., Pérez-Portabella Maristany, C., Xandri Graupera, J., Wouters-Wesseling, W., Wagenaar, L.

The effectiveness of oral nutritional supplementation in the healing of pressure ulcers.

J Wound Care, 2004. 13(8): p. 319-22.

Objective: To investigate the effectiveness of an oral nutritional supplement that is rich in protein and enriched with arginine, vitamin C and zinc on the healing of pressure ulcers.

Method: Thirty-nine patients with Grade 3 or 4 pressure ulcers were enrolled into this open intervention study. Subjects received an oral nutritional supplement daily for three weeks. Wound area and the wound condition of the ulcers were assessed weekly.

Results: After three weeks of supplementation, median wound area reduced significantly ($p<0.001$) from 23.6cm^2 (1.6-176.6cm^2) to 19.2cm^2 (1.2-132.7cm^2), a reduction of 29%. Median healing of wound area was 0.34cm^2 per day, taking approximately two days to heal 1cm^2. Within three weeks the amount of exudate in infected ulcers ($p=0.012$) and the incidence of necrotic tissue ($p=0.001$) reduced significantly.

Conclusion: Nutritional intervention in the form of a specific oral nutritional supplement resulted in a significant reduction in wound area and an improvement in wound condition in patients with grade III and IV pressure ulcers within three weeks.

Wound Area Measurements				
Measurement	Median (range)	Percentage (range)	Median cm^2 healed per day (range)	Median days to heal 1cm^2 (range)
Baseline	23.6 (1.6–176.6)	100	X	X
Week 1	23.6 (1.6–176.6)*	100 (58–127)*	0.00 (-8.4 to +0.9)	0.00 (-5.1 to 5.9)
Week 2	23.6 (1.6–176.6)*	88 (42–119)*	0.27 (-5.0 to +1.3)	1.78 (-29.7 to +71.3)
Week 3	19.2 (1.2–132.7)*	71 (9-133)*	0.34 (-3.6 to +0.9)	1.78 (-44.6 to + 17.8)

*$p<0.05$ analysed versus baseline by Wilcoxon's signed rank test

Benati, G., Delvecchio, S., Cilla, D., Pedone, V.

Impact on pressure ulcer healing of an arginine-enriched nutritional solution in patients with severe cognitive impairment.

Arch Gerontol Geriatr, 2001. 33 Suppl 7: p. 43-7.

Thirty-six in-patients with severe cognitive impairment and pressure ulcers were treated for two weeks with normal hospital diet (A), normal hospital diet plus oral supplementation with high protein calorie solution (B), normal hospital diet plus an oral supplementation with an iso-calorie and iso-protein solution enriched with arginine, vitamins and trace elements with antioxidant effect (C). Preliminary data show that patients with treatment C have a more rapid improvement in pressure ulcer healing than patients with treatment A and B.

HEALTH ECONOMIC STUDIES

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Cereda E., Klersy C., Serioli M., Andreola M., Pisati R., Schols J., Caccialanza R., D'Andrea F. for OEST Study Group.

Cost-effectiveness of a disease-specific oral nutritional supplement for pressure ulcer healing.

Clinical Nutrition 2015 1-7

Introduction: The Oligo Element Sore Trial has shown that supplementation with a disease specific nutritional formula enriched with arginine, zinc, and antioxidants improves pressure ulcer(PU) healing in malnourished patients compared to an isocalorice-isonitrogenous support. However, the use of such a nutritional formula needs to be supported also by a cost-effectiveness evaluation.

Methods: This economic evaluation e from a local healthcare system perspective e was conducted alongside a multicentre, randomized, controlled trial following a piggy-back approach. The primary efficacy endpoint was the percentage of change in PU area at 8 weeks. The cost analysis focused on: the difference in direct medical costs of local PU care between groups and incremental cost effectiveness ratio (ICER) of nutritional therapy related to significant study endpoints (percentage of change in PU area and ≥40% reduction in PU area at 8 weeks).

Results: Although the experimental formula was more expensive (mean difference: 39.4 Euros; $P < 0.001$), its use resulted in money saving with respect to both non-nutritional PU care activities (difference, -113.7 Euros; $P = 0.001$) and costs of local PU care (difference, -74.3 Euros; $P = 0.013$). Therefore, given its efficacy it proved to be a cost-effective intervention. The robustness of these results was confirmed by the sensitivity analyses.

Conclusion: The use of a disease-specific oral nutritional formula not only results in better healing of PUs, but also reduces the costs of local PU care from a local healthcare system perspective.

Schols J.M.G.A., J. M., Kleijer, C. N., Lourens, C.

Pressure ulcer care: nutritional therapy need not add to costs.

J Wound Care, 2003. 12(2), p. 57-61.

Fewer patients with pressure ulcers in Dutch nursing homes receive nutritional therapy via sip feeds, possibly because of cost concerns. But this therapy would not cost more if it reduced the duration of nursing care by even one day, this paper argues.

Summary of the main points
Nursing home patients are vulnerable to developing pressure ulcers. Yet in the Netherlands fewer are receiving nutritional therapy via sip feeds due to cost concerns.
The authors explored the actual costs of treating pressure ulcers using a mathematical model.
They monitored the basic nursing and extra costs of care in five nursing homes for 48 long-stay patients.
The same mathematical model was modified to make notional calculations on whether introducing sip feeds into treatment routines would add to these costs.
The authors found that if giving patients sip feeds reduced the total number of extra nursing days by only one day, then money could already be saved.
They believe their findings should be the starting point for further research into the beneficial effects of nutritional therapy on wound healing and that money would be saved in the longer term by using these treatments.

PREVENTION STUDIES

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PREVENTION STUDIES

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Hommel, A., Bjorkelund, K.B., Thorngren, K.G., Ulander, K.

Nutritional status among patients with hip fracture in relation to pressure ulcers.

Clin Nutr 2007. 26(5): p. 589-96.

Background & Aims: Patients with a hip fracture often have a poor nutritional status that is associated with increased risk of complications, morbidity and mortality. The aim of this study was to investigate the effects of an improved care intervention in relation to nutritional status and pressure ulcers. An intervention of best practices for patients with hip fracture was introduced, using the available resources effectively and efficiently with a not too complicated or expensive intervention.

Methods: A quasi-experimental study of 478 patients consecutively included between April 1, 2003 and March 31, 2004. A new evidence-based clinical pathway was introduced on October 1, 2003. The results from the first 210 patients in the control group and the last 210 patients in the intervention group are presented in this article.

Results: The total number of patients with a hospital-acquired pressure ulcer was in the intervention group, 19 patients, and in the control group, 39 patients ($p = 0.007$). No patient younger than 65 years developed a pressure ulcer. There were no statistical significant differences between the groups with respect to blood biochemical variables at inclusion. Patients in the control group had higher arm muscle circumference (AMC) ($p = 0.05$), calf circumference (CC) ($p = 0.038$) and body mass index (BMI) ($p = 0.043$) values. Abnormal anthropometrical tests of BMI, triceps skin fold (TSF) <10th percentile and AMC <10th percentile were found in 12 patients in the control group and in 4 patients in the intervention group. None of the 4 patients in the intervention group developed pressure ulcers. However, 2 of the 12 patients in the control group were affected.

Conclusions: It is possible to reduce the development of hospital-acquired pressure ulcers among elderly patients with a hip fracture even though they have poor prefracture nutritional status. Results in this study indicate the value of the new clinical pathway, as number of patients who have developed pressure ulcers during their stay in hospital has been reduced by 50%.

Houwing, R.H., Rozendaal, M., Wouters-Wesseling, W., Beulens, J.W.J., Buskens, E., Haalboom, J.R.

A randomized, double-blind assessment of the effect of nutritional supplementation on the prevention of pressure ulcers in hip-fracture patients.

Clin Nutr, 2003. 22(4): p. 401-5.

Background & Aims: Malnutrition is a risk factor for development of pressure ulcers (PU). Nutritional supplementation may thus reduce the incidence of PU. We investigated the effect of nutritional supplementation on incidence of PU in hip-fracture patients at risk of developing PU.

Methods: Hip-fracture patients (n=103) were included in this double-blind, randomized, placebo-controlled trial. They received 400 ml daily of a supplement enriched with protein, arginine, zinc and antioxidants (n=51) or a non-caloric, waterbased placebo supplement (n=52). Presence and stage of PU were assessed daily for 28 days or until discharge (median: 10 days during supplementation).

Results: Incidence of PU was not different between supplement (55%) and placebo (59%), but incidence of PU grade II showed a 9% difference (difference: 0.091; 95% CI: 0.07-0.25) between supplement (18%) and placebo (28%). Of patients developing PU 57% developed it by the second day. Time of onset (days) showed a trend (P=0.090) towards later onset of PU with supplement (3.6 ± 0.9) than placebo (1.6 ± 0.9).

Conclusions: Hip-fracture patients develop PU at an early stage. Nutritional supplementation may not prevent PU at this stage, but contributes possibly to a delayed onset and progression of PU. Nutritional supplementation may be more effective if initiated earlier.

CASE STUDIES

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CASE STUDIES

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Neyens J., Rondas A., van Leen M., Schols J.M.G.A.

The Effects of an arginine-enriched oral nutritional supplement on chronic wound healing in non-malnourished patients: a multicentre case study in the Netherlands.

EMWA Journal 2013. 13(2) p. 32-33.

Rationale: A series of cases has been conducted to record the effect of a specific arginine enriched oral nutritional supplement (ONS) in patients with pressure ulcers (PUs), leg ulcers or diabetic foot ulcers. Primary outcome parameters: 1) wound size, 2) patients' compliance and appreciation of ONS.

Methods: Design: case report study, approved by ethic committee, conducted in two Dutch nursing homes and one ambulatory wound centre. Twenty-two non-malnourished patients with a PU, leg ulcer or diabetic foot ulcer, existing > 3 weeks were included. All participants were offered 1-3 servings per day of a specific arginine enriched ONS in addition to their regular diet and standard wound care, for 12 weeks max. Besides patient characteristics, information on wound size (cm^2), product intake plus appreciation and photographs were collected every month.

Results: Fourteen females and eight males (mean age: 80) were included. Main diagnosis: arterial leg ulcer (n=5), venous leg ulcer (n=6), diabetic foot ulcer (n=2) and PU (n=9). Within 7-12 weeks, complete healing occurred in 11 ulcers, 10 showed a partial wound size reduction (35% to 75%) and one kept unchanged. Overall, the daily ONS servings, on average 400 ml, were fully consumed and the appreciation was good (n=22). Patient characteristics and wound healing over the course of the study are depicted in Table 1.

Conclusion: Nutritional support with a specific arginine-enriched ONS seems to be beneficial for the healing of different types of chronic ulcers in non-malnourished patients.

Table 1: Patient characteristics and pressure ulcer, diabetic foot ulcer, and leg ulcer healing

Patient Characteristic (N = 22)	
Mean age (range)	72,8 years (52-95)
Gender	7 Male, 15 Female
Mean BMI (range)	24,8 (20-38)
Mobility	Chairfast (N = 8), Walks occasionally (N = 9), Walks frequently (N = 5)
Existance of wound	< 4 weeks (N = 3), > 1 month < 3 months (N = 5), > 3 months (N = 14)
Wound type	PU (N = 7), DFU (N = 2), PU (N = 7), Arterial LU (N = 5), Venous LU (N = 8)
Mean wound size at start (range)	11cm^2 (1-46)
ONS per day	1 bottle (N = 7), 2 bottles (N = 14), 3 bottles (N = 1)
Healing	(N = 20)
Completely healed	N = 8
Partly healed*	N = 8
No effect	N = 4
Unable to follow up	N = 2

*unable to follow up with one patient after 4 weeks
BMI: body mass index, PU: pressure ulcer, DFU: diabetic foot ulcer, LU: leg ulcer.

REVIEW PAPERS

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REVIEW PAPERS

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Schols J.M.G.A., Heyman, H., Meijer E.P.

Nutritional support in the treatment and prevention of pressure ulcers: an overview of studies with an arginine enriched Oral Nutritional Supplement.

Journal of Tissue Viability, 2009. 18: 72-9.

Abstract

Under-nutrition, inadequate protein or poor protein and energy intake and unintended weight loss have been identified as independent risk factors for the development of pressure ulcers. Providing oral nutritional supplements (ONS) in addition to regular food intake seems a logical way to replenish body shortages of macro- and micro-nutrients as well as to supply extra nutrients for the preservation of skin tissue, strengthening of tissue resistance, and promoting tissue repair. To examine the effect of nutritional intervention in pressure ulcer care, clinical studies performed with a specific ONS enriched with arginine, vitamin C and zinc were reviewed. Six clinical studies that were performed with the specific ONS, identified via electronic and conference databases, were included in the review. Four studies examined the effects of the specific ONS in patients with pressure ulcers, while two studies examined the effects of the specific ONS in patients at high risk of developing pressure ulcers. The reviewed practice-based studies with the specific ONS specifically developed for patients with pressure ulcers show positive effects of this ONS on pressure ulcer healing and the ONS might potentially reduce the risk of developing pressure ulcers.

Cubitan is available in 3 flavours: Vanilla, Strawberry and Chocolate

Cubitan is suitable for patients with diabetes who have impaired wound healing

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