*i*CAHE JC Critical Appraisal Summary

Journal Club Details

Journal Club location	Daw Park Repat
JC Facilitator	Caroline Bartle
JC Discipline	Dietetics

Article/Paper

Cereda, E. Klersy, C. Seriolo, M. Crespi, A. & D'Andrea, F (2015). *A Nutritional Formula Enriched With Arginine, Zinc, and Antioxidants for the Healing of Pressure Ulcers*. Ann Intern Med;162:167-174. doi:10.7326/M14-0696

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Article Methodology: Randomised Controlled Trial

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International Centre for Allied Health Evidence (iCAHE)

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Ques No.	Yes	Can't Tell	No	Comments
1	✓			**Did the trial address a clearly focused issue?** To evaluate whether supplementation with arginine, zinc, and antioxidants within a high-calorie, high-protein formula improves pressure ulcer healing.
2	✓			**Was the assignment of patients to treatments randomised?** Allocation to the intervention groups was done by the coordinating center using a computer-generated randomization list (permuted-block randomization with varying block sizes). Random assignments were concealed in sealed envelopes.
3	✓			**Were all of the patients who entered the trial properly accounted for at its conclusion?** Yes, refer to figure: Study flow diagram on page 171 **Is it worth continuing?** YES
4	✓			**Were patients, health workers and study personnel 'blind' to treatment?** After assignment to interventions, a single person aware of treatment allocation at the coordinating center was responsible for asking the local pharmacy to remove the label from the bottles containing the experimental formula or to prepare the control formula. The oral formula was then supplied in unlabeled bottles to the patient's residence. Patients and outcome assessors (nurses and physicians responsible for wound care and dietitians) were blinded to treatment allocation.
5	✓			**Were the groups similar at the start of the trial?** Refer to table 2: Baseline Characteristics, by group on page 172

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6	✓			**Aside from the experimental intervention, were the groups treated equally?** All of the patients received wound care according to an evidence-based guideline (8). Local pressure to the areas was avoided as much as possible through the use of appropriate pressure-relieving devices and pertinent repositioning programs. Topical treatments were always applied by the same registered nurse (1 for each recruiting center), who specialized in wound care. The type of dressing and the frequency of its change depended on the PU depth and position, amount of exudates, type of tissue in the wound bed, and presence of infection. In the event of infection, systemic antibiotic therapy was administered according to antibiogram assay results. Wound debridement and negative-pressure wound therapy were considered when necessary. Before the trial started, the involved personnel of each participating center attended a training day to standardize the operating method. The training was repeated twice during the study.
7				**What are the results?** Supplementation with the enriched formula (n = 101) resulted in a greater reduction in PU area (mean reduction, 60.9% [95% CI, 54.3% to 67.5%]) than with the control formula (n = 99) (45.2% [CI, 38.4% to 52.0%]) (adjusted mean difference, 18.7% [CI, 5.7% to 31.8%]; P = 0.017). A more frequent reduction in area of 40% or greater at 8 weeks was also seen (odds ratio, 1.98 [CI, 1.12 to 3.48]; P = 0.018). No difference was found in terms of the other secondary end points. **How large was the treatment effect?** There is a treatment effect and it is significant, in favour of the experimental group (18.7 (5.7 to 31.8)). They do not report treatment effect
8				**How precise was the estimate of the treatment effect?** Not reported
9	Discuss in your Journal Club			**Can the results be applied in your context? (or to the local population?)** *Consider whether* □ *Do you think that the patients covered by the trial are similar enough to the patients to whom you will apply this?, if not how to they differ?*

10		**Were all clinically important outcomes considered?** *Consider* *Is there other information you would like to have seen?* *If not, does this affect the decision?*
11		**Are the benefits worth the harms and costs?** *Consider* *Even if this is not addressed by the review, what do you think?*
12		**What do the study findings mean to practice (i.e. clinical practice, systems or processes)?**
13		**What are your next steps? (e.g. evaluate clinical practice against evidence-based recommendations; organise the next four journal club meetings around this topic to build the evidence base; organize training for staff, etc.)**
14		**What is required to implement these next steps?**

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