International Centre for Allied Health Evidence

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*i*CAHE JC Critical Appraisal Summary

Journal Club Details

Journal Club	Lyell McEwin Hospital
JC Facilitator	Nicolette Varvounis
JC Discipline	Speech Pathology

Clinical Scenario

Review Question/PICO/PECO

P patients with head and neck cancer undergoing chemo-radiotherapy

I preventative behavioural intervention

C usual care

O muscle structure and swallowing function

Article/Paper

Mann, G , Crary, M, Schmalfuss, I & Amdur, R 2012 " Pharyngocise : randomized controlled trial of preventative exercises to maintain muscle structure and swallowing function during head and neck chemotherapy" , *International Journal of Radiation Oncology*Biology*Physics* , vol. 83, no. 1 pp. 210-219

Please note: due to copyright regulations CAHE is unable to supply a copy of the critically appraised paper/article. If you are an employee of the South Australian government you can obtain a copy of articles from the DOHSA librarian.

Article Methodology:	Randomised controlled trial
Journal Club Meeting on:	19th December 2012

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Ques No.	Yes	Can't Tell	No	Comments
1	√			***Did the trial address a clearly focused issue?*** The main aim of the trial was to examine the effect of preventative exercises for dysphagia in head and neck cancer patients undergoing head and neck radiotherapy. *Population:* patients with head and neck cancer who will be treated with external beam radiotherapy *Intervention:* high intensity behavioural treatment (Pharyngocise) *Comparison:* usual care and sham treatment *Outcomes:* muscle size and composition (primary); functional swallowing ability, dietary intake, chemosensory function, salivation, nutritional status, and the occurrence of dysphagia-related complications (secondary)
2	√			***Was the assignment of patients to treatments randomized?*** A total of 58 head and neck patients undergoing chemoradiotherapy were randomly assigned into three groups – the usual care (n=20), sham swallowing treatment (n=18) and active swallowing intervention (n=20), using a computer-generated blocked random numbers list.
3	√			***Were all of the patients who entered the trial properly accounted for at its conclusion*** Out of the 58 patients, 3 patients died and the follow up after 6 months could only be completed for 31 patients out of 55 (3 patients died and 24 patients were lost to the follow up). An intention-to-treat analysis was carried out, which means that all participants were analysed according to the group to which they have been initially allocated, whether or not they received (or completed) the intervention given to that group.
4	√			***Were patients, health workers and study personnel 'blind' to treatment?*** The patients and the speech pathologist who administered the treatment cannot be blinded. However, the speech pathologists who assessed the outcomes were blinded to treatment allocation.
5	√			***Were the groups similar at the start of the trial?*** The groups were similar at baseline in terms of age, gender, tumor size/site/location side, radiation dose administered, or provision of concurrent chemotherapy; homogeneity of groups could suggest that randomisation was successful.

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6	√			***Aside from the experimental intervention, were the groups treated equally?*** The participants in all three groups were treated by the same oncologists and received comparable chemoradiotherapy regimens. Exposure to medical intervention was also similar across groups.
7				***How large was the treatment effect?*** In controlled clinical trials, p-value is used to determine if the difference between or across treatment groups is likely to represent a real treatment effect or could have occurred simply by chance. A small p-value (<0.05) means that it is unlikely that the difference would have occurred by chance alone, so it constitutes evidence of a treatment effect. Higher p-values on the other hand, (≥ 0.05) indicate that the effect could have occurred by chance alone; therefore high p values are interpreted as a lack of evidence of a treatment effect. *Please consider the p-values reported in the study.
8				***How precise was the estimate of the treatment effect?*** Precision of the results (i.e. treatment effect) is determined based on the confidence intervals; most often the 95% confidence interval is used. Confidence interval describes the uncertainty inherent in the effect estimate, and is the range within which one can be 95% certain that the true average treatment effect actually lies. If the confidence interval is relatively narrow (e.g. 0.70 to 0.80), the effect size is known precisely. If the interval is wider (e.g. 0.60 to 0.93) the uncertainty is greater, although there may still be enough precision to make decisions about the utility of the intervention. In the current study, the confidence intervals for the primary outcome were not reported; hence the precision of the treatment effect cannot be determined.
9				***Can the results be applied to the local population*** ***Were all clinically important outcomes considered?*** ***Are the benefits worth the harms and costs?*** Journal club to answer