

# CAHE JC Critically Appraised Article Summary

## Journal Club Details

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<b>Date of submission</b>	2007
<b>Journal Club location</b>	Lyell McEwin Hospital
<b>JC Facilitator</b>	Matt Sutton

### Clinical Scenario

Is hydrotherapy better than usual care for pregnant women with LBP/pelvic pain?

### Review Question/PICO/PACO

- P** Pregnant women with LBP/pelvic pain
- I** Hydrotherapy
- C** Control/Usual care
- O** Pain, function, patient satisfaction, QOL, adverse events

### Article/Paper

Granath AB, Hellgren MSE & Gunnarsson 2006, 'Water aerobics reduces sick leave due to low back pain during pregnancy', *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 35(4): 465-471

**Article Methodology:** Randomised Controlled Trial

**Returned JC on:** 24 October 2007

**By CAHE staff member:** Mat Prior

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**The Centre for Allied Health Evidence (CAHE)**

Tel 08 8302 2769 Fax 08 8302 2766 Email [karen.grimmer@unisa.edu.au](mailto:karen.grimmer@unisa.edu.au)  
University of South Australia GPO Box 2471 Adelaide SA 5001 Australia  
To receive CAHE updates register online at [www.unisa.edu.au/cahe](http://www.unisa.edu.au/cahe)

Ques No.	Yes	Can't Tell	No	Comments
1	✓			The study asked a clearly focused question, i.e. "To compare the effect of a land-based, physical exercise program versus water aerobics on low back or pelvic pain and sick leave during pregnancy." (p465)
2	✓			Yes, the study was conducted as an RCT, and was suitable to compare one intervention (water-based exercise) against another (land-based exercise) Eligible women who agreed to participate in the study were randomised to either water-based (hydrotherapy) or land-based exercise according to date of birth.
3	✓			Whilst randomisation occurred according to date of birth, this method can be viewed as not being <i>true</i> randomisation. It is assumed that date of birth refers to day of month (eg 5 <sup>th</sup> , 7 <sup>th</sup> ), and it is possible that the sample could include a large grouping of subjects born on either odd- or even-numbered days. Perhaps a better method of randomisation would have been to allocate subjects to treatment groups by random number generator or similar method – however it should be noted that the groups in this study were comparable in size and similar in baseline characteristics.
4			✓	<p>It is stated that there was no blinding of randomisation (p466), and blinding of subjects to the type of intervention they received would not be possible. It is not stated as to whether measurement of sick leave, work outcomes and pain were conducted by a blinded evaluator (the obstetricians/physiotherapists), however it is assumed that this was not blinded.</p> <p>The only area in which blinding may have likely affected the study would be in terms of the participants themselves; i.e. the 'control' land-based exercise group knowing they are not receiving the water-based intervention being trialled, with this potentially influencing their work participation outcome.</p>
5	✓			All subjects who were initially included were accounted for at the study's conclusion (Figure 1, p. 468). However, from Figure 1, it appears as if the authors chose not to follow-up the subjects who did not receive their allocated interventions. If so, follow-up of this subgroup of subjects would still have been useful, and provided a useful comparison against those who did receive their intended intervention.

Ques No.	Yes	Can't Tell	No	Comments
6		✓		Outcomes were reportedly measured at regularly scheduled checkups at an antenatal care centre. Whilst most subjects would likely have volunteered having experienced pain, it is unclear as to whether subjects were specifically asked about pain or work absence, or needed to volunteer this information. This may make a considerable difference to the results of the study, particularly in regard to work absence. Moreover, if the subject volunteered being absent from work, it is unclear whether evaluators determined clearly whether that absence was specifically related to low back or pelvic pain.
7		✓		It is unclear as to whether the sample was large enough; with the authors stating that a sample size calculation was not performed. Numbers needed to treat (95% confidence interval) was calculated, however this is not reported. Later power analysis (reported in discussion p. 469) suggests that the study was potentially under-sized.  However, for practical purposes, it would seem that 266 analysed subjects (not all subjects were analysed – refer Figure 1) would be sufficient.
8				390 women were recruited into the study, however, due to a multitude of reasons (p. 467), only 266 received their intended allocated intervention and were followed through. Increased attendance was recorded for the water-based exercise group.  Subjects in the water-based exercise group reported significantly less low back pain compared to the land-based exercise group ( $p=0.04$ ), whilst the water-based exercise group also recorded significantly less sick leave due to LBP ( $p=0.03$ ), and sick leave in general ( $p<0.0001$ ). Indeed, no subject in the hydrotherapy group took sick leave due to LBP.  The rate of pelvic pain was comparable between the two exercise groups, with no significant difference in sick leave due to pelvic pain between the groups.  The bottom line result is that the study suggests that the use of water-based exercise for pregnant women can potentially reduce the prevalence of pregnancy-related LBP and associated sick leave.
9				Statistical analyses were performed, with p values listed for all significant differences between groups. However, non-significant differences are simply classified as such, with no presentation of a p value. The presentation of a p value, particularly if trending toward significance, may add to the worth of the information – especially in light of the possibility that the sample was not sufficiently large.  Moreover, additional information regarding pain severity and time off work due to LBP/pelvic pain, rather than simply the presence of pain or sick leave, would add greatly to group comparisons.

Ques No.	Yes	Can't Tell	No	Comments									
10			✓	<p>Not all important outcomes were considered in this study. That dropouts had a higher prevalence of multiparity is a potential confounding factor worth considering – particularly considering any possible cumulative risk for LBP or pelvic symptoms. As aforementioned, information regarding pain severity and time off work due to LBP/pelvic pain, would have been worthy of consideration. In addition, previous history of LBP should be a factor of interest, given the highly recurrent nature of LBP.</p> <p>However, the results are largely consistent with previous literature – water-based exercise demonstrated benefit compared to no exercise (Kihlstrand et al. 1996; Young &amp; Jewell 2005) (p466); however there is a relative lack of evidence comparing water-based exercise against other forms of exercise.</p> <p>There was a limited presentation of cost for the water-based intervention, with the authors only stating that it was “not costly” due to the number of participants; however a minimum number of participants required to offset costs is not determined. Before implementing such a program in any setting, the cost of doing so needs to be considered. The participants of the study are not considered to be different from pregnant women in other settings to whom the intervention may be targeted, and thus the results can be viewed as applicable to other settings. Obviously, however, the extent to which this intervention can be reproduced is determined by the available facilities.</p> <p><b>Statistical Info</b> The Chi-square test (X<sup>2</sup>) is a method of analysing the association between two variables. Note that the variables have to be categorical, i.e. Yes/No, On/Off, Pain/No Pain etc. This is because data is classified into distinct groupings for analysis. A simple theoretical example may be to look at whether land-based exercise participants or water-based exercise participants were more likely to experience low back pain. The ‘contingency tables’ mentioned in the article refers to how the data is arranged. For our example, the contingency table would look like this:</p> <table border="1" data-bbox="829 1724 1508 1859"> <thead> <tr> <th></th> <th>Low back pain</th> <th>No low back pain</th> </tr> </thead> <tbody> <tr> <th>Land exercise</th> <td>34</td> <td>100</td> </tr> <tr> <th>Water exercise</th> <td>19</td> <td>113</td> </tr> </tbody> </table> <p>Using the chi-square calculation, we can then determine whether there was a significant difference in the proportion of subjects experiencing low back pain (which there was).</p>		Low back pain	No low back pain	Land exercise	34	100	Water exercise	19	113
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