CRITICAL APPRAISAL SKILLS PROGRAMME
making sense of evidence about clinical effectiveness

CASP´s 11 questions to help you make sense of a trial

Crib sheet for: "Effect of firmness of mattress on chronic non specific low back pain: randomised, double blind, controlled, multicentre, trial.
Kovacs et al Lancet 2003. 362: 1599 –604

General comments

- Three broad issues need to be considered when appraising a trial:

  Are the results of the trial valid?

  What are the results?

  Will the results help locally?

  The 11 questions on the following pages are designed to help you think about these issues systematically.

- The first three questions are screening questions and can be answered quickly. If the answer to all three is "yes", it is worth proceeding with the remaining questions.
- There is a fair degree of overlap between several of the questions.
- You are asked to record a "yes", "no" or "can't tell" to most of the questions.
- A number of italicised hints are given after each question. These are designed to remind you why the question is important.
- The 11 questions were adapted from Guyatt GH, Sackett DL, Cook DJ, Users' guides to the medical literature. II. How to use an article about therapy or prevention. *JAMA* 1993; **270**: 2598-2601and **271**: 59-63, by the Critical Appraisal Skills Programme in Oxford (CASP).

A/ Are the results of the trial valid?

Screening Questions

1 Did the trial address a clear question? *Can you tell what* • *population was studied* • *ointervention was given* • *comparator was given* *outcomes were measured and when?*	**Yes** ✓ **Can't tell** ❑ **No** ❑ The population is adults with chronic (3 months or more) non specific low back pain while lying in bed and rising. The intervention is use of firm or medium firm mattresses. The "primary" outcomes are pain in bed, pain on rising, and disability.
2 Was the assignment of patients to treatments randomised?	**Yes** ✓ **Can't tell** ❑ **No** ❑ *Randomisation was done according to a table of random permutations before interventions were assigned. Randomisation was performed by staff distant from the research staff. Numbers were written on the outside of opaque envelopes. This number then corresponded to another number which was written on the inside of the envelope.*
3 Were all of the patients who entered the trial properly accounted for at its conclusion • *was follow up complete?* • *were patients analysed in the groups to which they were randomised?* •	**Yes** ✓ **Can't tell** ❑ **No** ❑ Flowchart showing progress of patients through the trial. 3 drop-outs shown. Intention to treat analysis performed. NB. Contradiction between text & flowchart & tables (last sentence of 2nd para. Pg. 1602) Detailed information about people who didn't participate and reasons for exclusion.

Detailed Questions

4	**Were patients, health workers and study personnel 'blind' to treatment?** • *were the patients* • *were the health workers* • *were the study personnel*	**Yes** ✓ or **Can't tell** ✓ **No** ❑ The patients, the health workers and the study personnel were blinded. *Officially only the person who did the randomisation knew which mattress participants received. Participants unaware that there were two types of mattress.* *Can check blinding by subjective perception of firmness of new mattress on table 2. Does it matter? If blinding broke down then it would have tended to favour firm rather than medium mattress because prior belief was that firm 'orthopaedic' mattresses were better.*
5	**Were the groups similar at the start of the trial?** • *In terms of other factors that might effect the outcome such as age, sex, social class*	**Yes** ✓ **Can't tell** ❑ **No** ❑ Yes Table 1 demonstrates comprehensive comparison of baseline demographics, which shows matching of the two groups. The authors themselves say the groups were similar 1st line para. 2 under results.
6	**Aside from the experimental intervention, were the groups treated equally?**	**Yes** ✓ **Can't tell** ❑ **No** ❑ Participants visited at home for entry assessment. All patients assessed at baseline and 90 days. Follow up and parameters assessed the same for each group.

B/ What are the results?

7 How large was the treatment effect? *Look at the result for each of the outcomes measured*	**8 How precise re the estimates of the treatment effect?** *What are the confidence limits or P-values for each estimate?*
Outcomes measured were:- • Improvement of pain while lying in bed on VAS OR 2.36 (1.13 – 4.93) • Improvement of pain on rising OR 1.93 (0.97 – 3.86) • Improvement of pain related disability (Roland Morris Questionnaire) OR 2.10 (1.24 – 3.56) However, there were two sets of results. The above results are detailed in table 3 and the abstract. There are different results in the text page 1602 at the bottom of the first column. The alternative results are :- • Improvement of pain while lying in bed on VAS OR 1.35 (0.77- 2.36) • Improvement of pain on rising OR 1.48 (0.81-6.68) • Improvement of pain related disability (Roland Morris Questionnaire) OR 2.10 (1.24-3.56) *Notice that the first set of results reach statistical significance for pain in bed and disabilit.y* *The authors may have used logistic regression inappropriately. After all they shouldn't really need to adjust for confounding if the trial is randomised and as they themselves note the two groupshave similar baseline characteristics. In addition, when using logistic regression the variables should be independent of each other, and they are not.* *Note also back to the power calculation on page 1600 statistical analysis, when the authors said they needed to show an improvement in each group of 20%. The improvement is actually4-5% so the study is under powered. In one calculation for improvement of pain on lying in bed, the difference from baseline is used, in the other the mean difference is used.*	• Improvement of pain while lying in bed on VAS OR 2.36 CI (1.13 – 4.93) p = 0.023 sig • Improvement of pain on rising OR 1.93 CI (0.97 – 3.86) p= 0.061 NSig • Improvement of pain related disability (Roland Morris Questionnaire) OR 2.10 CI (1.24 – 3.56) p= 0.006 sig

C/ Will the results help locally?

9 Can the results be applied to the local population? *Consider whether there good reasons to think that the patients covered by the trial may be importantly different from your own*	**Yes** ✓ **Can't tell** ❑ **No** ❑ Population is European people with back pain, so likely to be similar. However, we don't know the cultural situation as far as acceptability of treatment, current treatment practices etc. Professional patients if they have been in a trial once before.
10 Were all clinically important outcomes considered? *If not, does this affect the decision?*	**Yes** ✓ **Can't tell** ❑ **No** ❑ Measure of economic activity? Cost is considered. Total cost of intervention about €91,000 (cost of mattress €450) Pain Consultation rate in primary care would be useful.
11 Are the benefits worth the harms and costs? *This is unlikely to be addressed by the trial. But what do you think?*	**Yes** ❑ **Can't tell** X **No** ❑ No benefits demonstrated for superiority of either mattress