**Reviewer's report**

**Title:** Structured information during the ICU stay to reduce anxiety: study protocol of a multicenter randomized controlled trial

**Version:** 1  **Date:** 12 June 2009

**Reviewer:** Diana Elbourne

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I appreciate that the study has already received ethical and funding approval, so my comments to the authors are mainly asking for clarification.

1. The eligibility criteria (necessarily) restrict entry to patients are to fill in the questionnaires, without impaired cognitive/judgment ability. In the UK, such patients would often quickly be transferred off the ICU into a High Dependency Unit. Would it be very different in Germany? Or would HDUs also be included?

2. Some such patients may be cognitively OK but physically unable to write. It would be a shame to exclude them if some way could be found to help them to sign forms/complete the questionnaires.

3. The study has cities AND centres as stratification factors – surely it is not sensible to have both in a trial of this size?

4. Patients who are informed beforehand (elective/non-emergency) seem to be in such a different category from the emergency group that I feel this should be a stratification factor, and used in the analysis either as a covariate or a separate sub-group analysis.

5. In many cases, the patient will be accompanied for much of the time by one or more close relatives or friends. Has consideration been given to how such people would be involved in this trial? Might they be present at the request for informed consent and/or at the intervention or control conversation(s)? They could then enhance the messages.

6. Might the key aspects of the conversations be made available in written form? – it is often hard enough to remember information in normal circumstances, let alone in an ICU!

7. It would be helpful to readers if the protocol could include
   a. A patient information letter
   b. Copies of the relevant questionnaires

8. Roughly how long will the questionnaires take to fill in on each occasion?

9. Is there any scope for staff/researcher assessment/observation of anxiety (in addition to patient-completed questionnaires)
10. Are there plans to feed back the results of the study to study participants?

11. ANCOVA is a sensible strategy but perhaps elective/emergency, or time from admission to ICU (or some other important predictors of anxiety known at baseline) could be additional covariates?

12. Might there be scope for a per-protocol analysis (in addition to the primary intention to treat analysis)?

13. There needs to be some discussion about how deaths will be handled
a. in the analysis
b. in the conduct of the trial (I'm particularly interested in this personally because I am in the middle of a study looking at bereavement following entry into neonatal ICUs http://www.bracelet-study.org.uk/)

14. I was not clear about the ‘custodian’. If this is someone who is a guardian because the patient is not considered ‘competent’? If so, they wouldn’t be eligible to participate anyway.

15. How long is it planned that the trial will run for?

16. At various points the terms verbal/non-verbal and oral are used. Taking the terms literally, verbal is about communication in words rather than, say, in sign or body language; oral is by mouth ie spoken rather than written. I'm not always clear whether the terms are used in their correct meanings in different places.