Reviewer's report

Title: Efficacy of a pressure-sensing mattress cover system on reducing interface pressure and incidence of pressure ulceration: Study protocol for a parallel two-group randomized trial design

Version: 1 Date: 6 May 2015

Reviewer: Jo Dumville

Reviewer's report:

1. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?

* More information is required on the type of randomisation that will be used. The name of the on-line tool should be provided and how it ensures adequate sequence generation and allocation concealment explained more fully.

* There is no information about how missing data will be dealt with and it is not explicitly stated that an ITT analysis will be conducted.

* I think that the trial authors should justify more explicitly why they are not undertaking blinded outcome assessment for clinical data.

* It is not clear what grading system is being used to assess the pressure ulcers for the outcome.

* The protocol describes that a sub-set of 60 participants will be followed for longer than 72 hours. It is not discuss why this is occurring, what these very underpowered data will add nor how these participants will be chosen.

* It is unclear what baseline data are being collected.

* I think it is really important to note that the title suggests pressure ulcer incidence is being measured but actually these data are being presented as part of a composite outcome which includes more than just pressure ulcer incidence. This potentially makes the title misleading.

* It would be useful to the readship I think to explain or justify why the short follow-up and composite outcomes have been selected in this study. My concern is that the composite outcomes are a collection of important outcomes and that grouping them together is of limited use clinically. Ultimately, it is ulcer incidence that is of clinical interest and I am not clear how the composite outcomes will help inform decision making in the field. Do the authors anticipate that data from this study could be included in the current relevant Cochrane review?

2. Is the writing acceptable?

Yes - some light editing is required and the references need checking. The authors use the term subjects which I think should be avoided. I assume this will
be change to something less outdated - like participants.

I think that the authors should also check through their introduction. For example - this sentence below was confusing to me as - it starts of talking about a prospective controlled study and then seems to continue talking about this study but references a study with historical controls. –

A recent prospective controlled study indicated that CPI could decrease the incidence of pressure ulcers in a medical intensive care unit. Over the two-month study period, only one patient (0.03%) in the group of patients placed on beds with a continuous bedside pressure mapping (CBPM) system developed a pressure ulcer while 16 patients (5%) of the historical control group of patients placed on the same beds without CBPM (P=0.001).

Also the introduction states the figures below.

Annually, pressure ulcers affect an estimated 250,000 to 500,000 individuals in Canada with an overall estimated prevalence of 26.0% in health-care institutions1. I think it’s important to note that this reference includes studies that are relatively old. The studies that were conducted in acute care were undertaken in years 1990-2002 - so the estimates are a minimum of 13 years old. It is also unclear if Grade I ulcers are being included in these prevalence estimates. It seems a relatively minor point but a lot of wound care studies start off by reporting prevalence or incidence figures that are either out-dated or which stem from poorly conducted prevalence studies. In a large trial of pressure ulcer prevention in the UK the incidence of grade 2 pressure ulcers or higher grades was 10-11%.

The authors also need to ensure that the introduction is fully reference – for example I think that the following statements need references adding to the relevant guidance.

The National Pressure Ulcer Advisory Panel recommends repositioning hospitalized patients every two hours (ref) while the European Pressure Ulcer Advisory Panel suggests every four(ref).

The authors might also consider including the findings of the relevant Cochrane systematic review on repositioning in the introduction as presentation of recent systematic review data in the field is important.