Sundberg et al. present a pilot trial consisting of what is described as a “pragmatic randomised clinical trial” on the treatment of both acute and chronic neck and back pain patients, conducted at four primary care units in suburban Stockholm.

The stated objective of the pilot trial was to explore the general clinical effectiveness of conventional care combined with complementary therapies in an integrative medicine (IM) model, compared to conventional care alone. This is an unconventionally defined objective, since the purpose of pilot trials is not to test the hypothesis of the subsequent main trial (effectiveness of IM compared to conventional care), but rather to obtain missing basic data, e.g. to estimate the differences in treatment outcomes that may realistically be expected, for the purpose of calculating the sample size for the main study. Since no such data are yet available in the literature the authors were indeed unable to calculate sample size with any degree of confidence. However, a pilot trial could conceivably have other objectives as well. Therefore the authors should define the ultimate object of the pilot trial more clearly.

Eighty patients with acute or chronic neck and back pain were recruited. Since it was not clear whether IM is equally effective for acute and chronic pain, both types of pain were included in the study. This should be more clearly pointed out.

The 80 patients were randomised by a computer-generated procedure. Nevertheless, only 36 patients were allocated to the conventional primary care arm, while 44 were allocated to the IM arm. This is not a distribution that would normally be expected from a centralised randomisation procedure. The authors should explain this difference.

Outcome data were collected 16 weeks after randomisation. After 16 weeks there were 9 (25%) drop outs in the conventional arm and 8 (18%) in the IM arm. In the “Statistical analysis” part the authors state that all patients were kept in their assigned groups for the final analysis, in accordance with the ITT principle. However, the ITT principle also requires that all randomised patients be included in the statistical analysis. This the authors do not do. Rather, all patients lost to follow-up were excluded from the final analysis. The problem with this approach is that drop outs and other protocol violations are not simply events by chance, but are related to the respective treatment. If drop outs are excluded from the
statistical analysis, the patients who remain in the study (who will generally be the more satisfied ones) will result in massive distortion of study results toward more positive treatment effects. If the intended objective of the pilot trial (which the authors still need to define) were in fact the estimated magnitude of the treatment effect, then such a distortion of the results would be of major importance. But even if the objective of the pilot trial were something entirely different, at the very least the very positive interpretation of the outcomes in the “Results” section (“statistically significant improvements within both groups of care at follow-up after 16 weeks”) should be corrected. This means that the authors need to either re-analyse their data to include all randomised patients, or they must revise the central conclusion of their pilot trial concerning what are described as statistically significant improvements.

A very large number of diverse outcomes are included in this study. There is nothing wrong with this. However, the authors should clearly establish at the outset which of these many outcome variables is intended to serve as the primary outcome in the subsequent main trial.

The authors state that they used a p-value of <0.006 for the Bonferroni correction, which corresponds to the testing of 8 variables for the same patient pool. However, in Table 2 there are 12 variables that are tested, and one would therefore expect a corrected p-value of <0.004. Moreover, stating a p-value of 0.000 in Tables 2 and 3 is nonsensical, even if SPSS does give this value. What SPSS means by this is that p < 0.001. The “0.000” p-values in these tables must be corrected.

For the comparison of baseline variables, it is not really necessary to give p-values, since one would not expect a p-value of <0.05 after randomisation in any case (even though it could occur after randomisation in rare cases).

In the “Statistical analysis” section, the authors state that the dichotomous variables were analysed by logistic regression. It is absolutely essential to indicate whether these analyses were univariate or multivariate. Also, every reader will justifiably expect a precise description of the model underlying the logistic regression (definition of outcome variable and independent variables). This information is not apparent in Table 3.

In summary, the authors need to specify the following:

• what is the actual objective of their pilot trial
• which variable is intended to serve as the primary outcome measure in the subsequent main trial
• what are the treatment outcomes in the two treatment arms when drop outs are included in the final analysis in accordance with the ITT principle.

The authors should also address or correct all of the above-mentioned other issues in their manuscript.

**Level of interest:** An article whose findings are important to those with closely
related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.