Reviewer's report

Title: The third Symptom Management Research Trial in Oncology (SMaRT Oncology-3): a randomised trial to determine the efficacy of adding a complex intervention for major depressive disorder (Depression Care for People with Lung Cancer) to usual care, compared to usual care alone in patients with lung cancer.

Version: 1 Date: 26 June 2009

Reviewer: Gordon Doig

Reviewer's report:

Trials Protocol MS 1533036150272635: “The third Symptom Management Research Trial in Oncology (SMaRT Oncology-3): a randomised trial to determine the efficacy of adding a complex intervention for major depressive disorder (Depression Care for People with Lung Cancer) to usual care, compared to usual care alone in patients with lung cancer.”

This is a very well written protocol paper however I have concerns regarding the lack of details describing the planned analysis.

I note that you intend to develop a “detailed Statistical Analysis Plan”. Due to my concerns surrounding the vague nature of the reported intended analysis based on ‘the per protocol principle’, with no details regarding exclusions from analysis, I will reserve judgment on this submission until it is accompanied by a ‘detailed Statistical Analysis Plan’.

Upon re-submission, please also include the following details:

Sample Size
Please report whether your outcome is treated as a rate or a continuous variable. If it is treated as a continuous variable, please report the SD assumed for your sample size calculations.

Lost to follow-up
Please report all assumptions that will be made concerning patient data that is lost to follow up. For example, if a patient misses one phone interview, will you impute a response, carry their last observation forward or weight their ‘average’ primary outcome for number of observations?
I wish you all the best in the conduct of your trial.

Gordon S Doig