Reviewer's report

Title: Need for Exercise among Patients with Hypertension and Renal Disease (NEPHROS Trial): Randomized Controlled Trial

Version: 1 Date: 13 January 2012

Reviewer: Malinee Laopaiboon

Reviewer's report:

The paper is interesting however there are some issues that need to be considered as followings.

1) The title of "Need for Exercise among Patients with Hypertension and Renal Disease (NEPHROS Trial): Randomized Controlled Trial" may not consistent with the study design. Need for exercise.....may be answered by using descriptive design to explain the need for exercise... I suggest to modify it to be "Effect of exercise on increasing kidney function among Patients with Hypertension and Renal Disease: Randomized Controlled Trial".

2) Sequence of the methodology should be modified in a proper way of RCT design. Suggestion is a) Design and setting, b) Recruitment and eligibility including inclusion and exclusion criteria (with sample size calculation, this can be add to the analysis subheading), c) Random allocation, including how to generate list random numbers and allocation concealment, d) intervention and procedure, e) outcomes (primary and others) with description of their measurements f) data collection and g) data analysis.

3) The author calculated 63 subjects for each treatment group and expanded to be 100 each. Even the reasons are presented, it is unclear whether the increase number is appropriate. The author should provide more concrete information, e.g. expected % of loss to follow-up, etc.

4) Sample size was calculated by using the estimate of primary outcome, glumeruler filtration rate measured at the end of 16 weeks. This is not consistent with the interest repeated measures of the outcome at before, 8 and 16 weeks after starting interventions and 8 weeks after the end of intervention. The estimate sample size may be inappropriate to answer research question.

5) In the random allocation on page 8-9, the authors present detail of baseline characteristics and how data will be collected. This is not the stage to present the information. However, it is unclear whether random allocation will be concealed before providing intervention.

6) The author present block of six will be generated for balancing sample size between the two groups. I wonder whether it can be apply for the 100 sample size of each.

7) Duration of intervention should be clearly presented.

8) Quality of life is mentioned as one of the primary outcomes but it is not
information in the primary and secondary outcomes.

9) Statistical analysis is unclear which outcomes will be analysed by which statistic for intervention comparison. In the RCT we don’t need to do the comparison analysis of baseline characteristics between the groups. It is not the research objective.

According to these comments I am not sure whether the protocol is clear enough to provide a good research evidence in the future.

Level of interest: An article of importance in its field

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