Reviewer's report

Title: The Efficacy of Motivational Counselling and SMS-reminders on Daily Sitting Time in Patients with Rheumatoid Arthritis: Study Protocol for a Randomised Controlled Trial

Version: 3 Date: 14 July 2014

Reviewer: Marissa Lassere

Reviewer's report:

1-Will the study design adequately test the hypothesis?
Yes
The question of whether a sustained (to 18 months) improvement in the CV risk profile results from the 16-week intervention is an interesting one. Patients randomized to counseling and SMS-reminders vs control (usual care). The hypothesis is that the intervention will reduce inactivity and thereby reduce CV risk, consistent with the possibility that the increase in CV risk in RA is, in part at least, due to inactivity. However, to substantiate a clinical value the reduction in inactivity needs not only to be shown but the less inactivity needs to be shown to translate into a reduced CV risk via a CV outcome study or via an improvement in CV risk profile. [This is the classic surrogate scenario: Inactivity associated with increased CV disease risk does NOT, without evidence, imply that a reduction in activity will be associated with a reduction in CV disease outcomes.] The authors have the option to include this in the discussion this or not. It is not essential.

2-Sufficient detail to allow replication?
Yes, if below is clarified

3-Statistical analysis appropriate? Essential clarifications:
Can you clarify which specific primary endpoint was used in the pilot study on which the statistical power of this study is based.
The primary outcome is the ACtivPAL@3 TM Activity Monitor ("objectively measured" is called the primary endpoint on page 6). I assume that it was ACTivPAL rather than patient self-reported sitting time that is used in the power calculation. Please provide further information on powering of the trial to clarify in the manuscript. On page 11 both the ACTivPAL and the self-reported sitting time are described as primary. What happens if a win in one but not the other? Please clarify and discuss in the manuscript.

4-Writing acceptable?
Yes

(i) Please discuss whether wearing ACtivPAL@3 TM Activity Monitor may be
seen as an 'intervention' in itself therefore reduce the size of the between arm difference. Is this something that needs to be factored into the sample size calculation? Please comment and clarify in the manuscript.

(ii) Although the assessors are blind the patients are not. Please clarify this in the manuscript and discuss whether lack of double blinding is influential or not in the context of this trial.