Reviewer's report

Title: SMART: Self-Management of Anticoagulation, a Randomised Trial

Authors:

Dr David A Fitzmaurice (D.A.Fitzmaurice@bham.ac.uk)
Ellen T Murray (E.T.Murray@bham.ac.uk)
Miss Deborah McCahon (D.Mccahon@bham.ac.uk)
Christopher J Fuller (C.J.Fuller@bham.ac.uk)
Prof Richard FD Hobbs (F.D.R.Hobbs@bham.ac.uk)
Teresa F Allan (T.F.Allan@bham.ac.uk)
James P Raftery (J.P.Raftery@bham.ac.uk)

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Level of interest: A paper of considerable general medical or scientific interest

Advice on publication: Accept after discretionary revisions

The present manuscript is the study protocol of SMART: Self-Management of Anticoagulation, a Randomised Trial. This important study randomized patients in primary care, to either self-monitoring and management of anticoagulation or standard care.

This is a well-written manuscript however some concerns exist, as noted below.

Specific Comments

INTRODUCTION
A brief description of the results of the previous observational studies should be included in the Introduction and more details and / or a table in the Discussion.

AIM
It should be pointed out that only patients who were on warfarin for at least six months were included. Therefore, the aim of the study was to examine "the clinical and cost effectiveness of patient self-management for oral anticoagulation in comparison to standard care "in patients who are already on stable (?) long term anticoagulation therapy".

PATIENT RECRUITMENT
It would be very useful to have a figure with the study design.

According to the study design "all" GP patients were candidates for the study. The term "Patients only entered the study if both the research team and the patients own GP agreed that there was uncertainty as to which model of care would provide the best therapeutic control", is not clear. (Criteria for uncertainty ?: nursing home, etc ?). Rephrase.

The inclusion and exclusion criteria and the endpoints of the study should be clearly defined. Are the
haemorrhagic and thrombotic complications an endpoint?
The monitoring from GP records is not enough for minor complications. Did the postal questionnaire have a section on complications?

The parts on "Information sessions" and "Patient training" could be reduced.

STATISTICAL ANALYSIS

The secondary outcomes of patient satisfaction on either the Physical Component Summary (EQ-5D) or the Mental Component Summary (SF-12) are very important. However, the description of the questionnaires in a few sentences (with references) is necessary.

DISCUSSION
Since the study is nearly completed, the "flow diagram" of the trial should be included in more details according to the revised CONSORT statement.

Competing interests:
None declared.