Reviewer's report

**Title:** Optimizing Prescribing for Older People in Primary Care, a cluster randomized controlled trial: OPTI-SCRIPT study protocol

**Version:** 2  **Date:** 11 December 2012

**Reviewer:** Rolf Wahlström

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**General**

This study focuses an important aspect of general practice: to reduce potentially inappropriate prescribing (PIP) among elderly (#70 years), and thereby risks of harmful interactions or reactions. The tool to achieve this is a web-based treatment algorithm to be used by GPs when reviewing individual medications in direct contact with the patients. In my judgement this algorithm and the recommendations for its use are the main intervention components that will be tested. The visit by the pharmacist in each practice at the start of the study seems mainly to focus on demonstrating the algorithm and give instructions how the medication review process should be undertaken, and are therefore not examples of academic detailing. An additional part of the intervention is that patients will be provided with tailored information leaflets.

Apart from this, the study protocol is well designed, although there are some essential aspects that should be clarified before this manuscript can be accepted for publication.

**Major revisions**

**Title**

The title is very broad. My recommendation is to mention the intervention content in the title, for example: “... through a medication review process using a treatment algorithm”.

**Aims**

In line with my reasoning above, I think the aims should be revised. In my assessment the authors have not shown that this is a particularly complex intervention for the participating GP. He or she will get access to a web-based algorithm to be used for medication reviews of preselected patients. Alternative treatment options will be available and the GP has just to decide, in agreement with the patient, to follow these or not.

**Methods**

The main issue that must be clarified is what is meant by “practices” and what is meant by “GP”. It seems on the one hand clear that practices are the unit of randomisation, not specifying whether they are solo practices or group practices.
This would mean that the ten patients that will be recruited per practice could be managed by more than one GP. However, on the other hand, it is somewhat ambiguously mentioned that outcome forms will be “… completed by GPs at the end of each of the 10 medication reviews they conduct for the 10 recruited patients”, and further that the evaluation interviews with GPs “… will be completed within one month of them completing all 10 medicines reviews”.

Another issue that should be clarified is the number of patients that will be on the lists received by the “control group GPs”. Will it be ten patients per practice as I understand is the case for the intervention practices, or will it in both arms be all patients with PIPs from the list of 50 patients provided by each practice for the baseline.

Outcomes measures and sample size
The first primary outcome is the “Proportion of patients with PIP”, but this outcome is not quite clear to me. Is it at all related to “level of PIP in primary care”. First, proportion of what? Of the ten patients recruited per practice? Second, if assuming that it means the proportion of the ten patients (and bearing in mind that all these ten patients have at least one PIP at the start of the intervention), a possible result could be that there is a substantial reduction of all PIPs among these ten patients but all of them still have at least one PIP. So the effect of the intervention would then be no change for the primary outcome.

The authors have used this outcome for one of the sample size calculations, and by doing so they have chosen the scenario, that may give the lowest numbers of participants required for the assumed ten percent absolute reduction, given that their assumption for the calculations seems to be that there is no change in the control arm. However, this latter assumption is only valid if there is no change in the control arm. This has not been stated in the text, but must be clarified and commented.

The same relates to the second primary outcome where it seems obvious that the authors haven’t assumed any change in the control arm, as they equal a 30 percent relative reduction from a baseline of 1.45 PIP per patient with 0.43, thus giving no room for a reduction in the control arm. This must also be clarified and commented.

In my view, I find it quite unlikely that there would be no change among GPs in the control arm as they know that they are participating in this study, as they also know the objectives and outcome measures, and as they will receive a personalised list summarising PIPs. Admittedly, the authors have addressed this issue in relation to describing reasons for the additional contemporaneous national control, but I cannot see that this has influenced the sample size calculations. A clarification is needed.

Intervention
As mentioned above, the authors should give much clearer arguments for their claims that this is a multifaceted, complex intervention.
Further, it would be of value to provide more information about how the medication review and the use of the algorithm will take place during the specially scheduled consultations. Will the GPs in any way be forced to follow the study protocol, or can they ignore this without any reminders or alerts? Are they advised to schedule a certain time for the consultation or is it up to them to decide? Has the use of the algorithm been tested and with what result? Is the patient supposed to take active part in the use of the algorithm? Is it formatted in such a way that this would be feasible?

Finally, it would be useful if the authors could add information about how the intervention will be monitored during the phase when the GPs are performing the medication reviews. Will there be any control of how the protocol is followed or will the researchers abstain from any inference? Will participating GPs in the intervention arm be contacted if they don’t send the outcome forms as intended?

Discussion:
This study can be considered artificial in the sense that outside preparations are conducted to supply the GP (and the patient) with both essential information and a tool for decision-making to be used at a specifically scheduled visit in order to carefully consider the appropriateness of the individual patient’s medicines. It is in fact this whole process that is evaluated. The authors must therefore make clear in the Discussion whether they expect this whole process (sending lists for evaluation to an external body; feedback to prescribers; scheduling time for medication review; conducting the review with all eligible patients) to be feasible and sustainable, or whether the process has to be developed further to be applicable in routine care (e.g., by installing an algorithm directly into the medical record with prompts and warning signals).

Minor revisions
General: The authors should follow the journal’s Instructions for Style and language, in particular not capitalize words in title or headings and sub-headings; use the same spelling (e.g., minimization – minimisation) and the same expressions (e.g., medicines review – medication review) consistently; avoid paragraphs with only one sentence in running text; and conduct proper proof-reading to avoid spelling and spacing mistakes, in particular in the figure and tables, but also in the text (e.g., form instead of from).

Abstract:
Background: Clarify the age group of “older people”, as defined in the main text. Add that the prevalence of PIP relates to this age group. Clarify what “prevalence of PIP in Ireland is estimated at 36%” means. My understanding is that it means the number of individuals in the population in the defined age group that regularly “receives” at least one inappropriate medication, but this is not clearly stated.

Background:
Clarify what is meant by “the prevalence of PIP in older people (aged # 70 years)
in Ireland has been estimated at 36%", as commented above. Reference #11 is not totally clear whether it refers to the whole population or those (97%?) who are listed in the database used to retrieve information about medication.

Discussion:
Authors are recommended to add comments to some of the issues raised in this review, as indicated above.

Abbreviations:
All abbreviations should be explained when used first time (e.g., HRB).

Table 2:
It should be clearly indicated how prevalence was defined.

Table 3:
Should be shown on a separate page.

References:
Needs to be totally revised. There are numerous errors.
The journal’s Instructions have not been followed for any of the references regarding the following aspects:
1. Last author’s name should be followed by a colon;
2. Titles of articles should be in bold;
3. Journals' names should be in italics;
4. Journals' names should be followed by a comma;
5. Volume should be in bold;
6. Last page number should also be shown in full;
7. Titles of books and reports should be in italics.
There are also other examples where the Instructions have not been followed:
All authors’ names should be listed up to 30: Ref #9,16,22-24,26.
Journal names should be abbreviated: Ref #6,11,12,15,18,20,21,23,24,26,41,42-47.
Other errors:
Not necessary to add doi if other characteristics of the journal are present: Ref #12,15,41.
Not necessary to mention that a book can be accessed from internet: Ref #40.
Incorrect punctuation of source of books: Ref #1,14,27,40.
Not showing date of access to website: Ref #16,34.
Year of publication shown twice: Ref #22-25,28-31,38,39,44,45.
No volume and page numbers: Ref #23.
Incorrect pages: Ref #26.
No source of reference: Ref #35.