Author's response to reviews

Title: Impact of drug reconciliation at discharge and communication between hospital and community pharmacists on drug-related problems: study protocol for a cluster randomized cross-over trial

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Author's response to reviews: see over
Dear Editor,

Please find the revisions to my article [MS: 1735181259126036]
Impact of drug reconciliation at discharge and communication between hospital and community pharmacists on drug-related problems: study protocol for a cluster randomized cross-over trial
Xavier Pourrat, Clarisse Roux, Brigitte Bouzige, Valérie garnier, Armelle Develay, Benoit Allenet, Martial Fraysse, Jean-Michel Halimi, Jacqueline Grassin and Bruno Giraudeau].

All modifications in the manuscript were done using “tracked changes”.
Notice that one modification has been done in the protocol with adding a new centre. So we have now 22 centres instead of 21 and 46 units instead of 42; the manuscript was changed according to the modification.

According to editor comments the follow modifications were done as follow:

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format: study protocol for a randomized controlled trial.
   Title was changed as:
   Impact of drug reconciliation at discharge and communication between hospital and community pharmacists on drug-related problems: study protocol for a cluster randomized controlled cross-over trial

2. Please include the date your study was registered with your trial registration number at the end of your Abstract.
   We added “This study was reported to ClinicalTrials.gov (no. NCT02006797) on December 5th 2013”. This piece of information was also added in the main text.

3. Please include the names of all ethical bodies that approved your study in the various centres involved, along with the reference numbers given. If you do not wish to list them all in the methods section, please include the list as an additional file and refer to this in the methods section.
   As previously explained, French legislation requires only one ethic committee’s agreement for all centres. We have specified this point in the manuscript:
“The local ethics committee –CPP TOURS – Region Centre – Ouest 1- approved the study for all centres. Indeed, French legislation requires just one ethic committee’s approval for all centers. We were asked by the CPP TOURS – Region Centre – Ouest 1 to provide a signed commitment from all the heads of the involved care units. In table 1 we report the list of those units.”.

4. Please remove your Conclusion section and incorporate this information into your Discussion.
The manuscript has been re-formatted as requested.

5. Please include a figure title and legend section after the reference list.
These elements have been added.

Reviewer's report:
I read the cluster cross-over trial paper from Dr. Xavier Pourrat et al. about drug reconciliation at discharge, and I think it is very well designed. It deserves publication in Trials.
We first would like to thank the reviewer for this kind comment.

Nevertheless, I would like to make some comments to the authors in order to help them to improve study replication and potential impact as well as to clarify their dissemination policy.

- Major Compulsory Revisions
Please provide details about your dissemination policy, such as those suggested in SPIRIT item 31.
We added the following section in our manuscript:

Dissemination
The scientific committee will be in charge of the publications to report the results of the present study. Reports will follow the CONSORT Statement and its extensions (for both cluster randomized trials and non pharmacological interventions) as well as the TIDER checklist.
Please conciliate your sentences about blinding on page 7, line 12 (blinded rater committee) and on page 8, line 2 to the end of page (fully open).

The primary outcome is being assessed in a fully open way. However the potential medical impact of the DRP (which is a secondary outcome) is being assessed in a blinded way. We have specified this point in the manuscript.

Your main variable specified in page 7 is a sum of potential severities for each DRP, but your sample size rationale hypothesizes a difference from .45 to .60 in the DRP proportions. Please clarify.

We have specified in the manuscript that:
“Severity of identified DPR will be one of the secondary outcomes.”

Therefore, the primary outcome remains a binary composite outcome.

In both discussion sections you specify that “It will allow for identifying the type of patients in France for which the intervention is most relevant”. Please, either remove it or state variables and methods for this objective as well as its nature (secondary? exploratory?)

We changed the sentence by “The subgroups study (<>75 years old, <> 4 drugs, expensive/not-expensive medication and surgery/medical-unit and plan/non-planned hospitalization ) will evaluate the patients for which the process would be efficient”

- Minor essential Revisions

In order to improve potential replication and impact, please consider if the CONSORT extension for non-pharmacological interventions as well as the TIDIER and SPIRIT guidelines can provide useful insights.

We indeed have planned to use the CONSORT Statement and its extensions to report the results of our trial. Both the extension for cluster randomized trial and the extension for non pharmacological treatments will be used. We have also planned to use the TIDER checklist.

These elements have been added in the Dissemination section.

- Discretionary revisions

Please, review your sentences in page 10 “This study will investigate an the effect of HP…” and “Patients in the intervention group the need to spend only…”
Please, consider changing in page 10, “and not a short mean length of stay (average from 5 to 11)” to “and a mean length of stay from 5 to 11”.

My best wishes for the next phases of your meritorious work.

Many thanks!