Reviewer's report

Title: Project HELP: A study protocol to pilot test a shared-decision making tool about treatment options for patients with Hepatitis C and Chronic Kidney Disease

Version: 0 Date: 13 Dec 2017

Reviewer: Darren Churchward

Reviewer's report:

Politi et al. present a comprehensive overview of the design and methods of their study, aimed at producing an effective decision aid for patients with CKD and HCV. The authors provide an extensive background of the development of HCV therapies and its relevance to CKD patients. They effectively highlight the important decisions which face clinicians and patients in selecting the most appropriate treatment options. Furthermore, the authors justify the need for improving patient involvement in the treatment process and highlight how a decision aid may be effective at providing the means for this.

This study will help to develop a tool which could help educate and empower HCV + CKD patients, potentially having a significant impact on the wellbeing of these patients. However, I believe in its current form the manuscript does raise some minor questions and comments, which are listed below:

Introduction

Line 119 has a full stop in the middle of the sentence instead of a comma.

Lines 127-130, are there any references to support these points which the authors can include?

There is a spelling mistake at the end of line 132 'ta'.

Methods

The authors state on line 199 that patients will be stratified into CKD stage. Will each strata have a target for recruitment or will this just be a covariate in analysis? If a covariate then perhaps this is best stated in the data analysis plan.
Data analysis plan

On line 241 the authors state that up to five independent covariates will be included in a multivariable regression but then only list three covariates. Could you please list which other covariates you plan to include in your model, or amend the wording.

I would also question whether the sample size is large enough to guarantee an unbiased estimate of regression coefficients whilst controlling for this number of covariates; is there a reference which could be included to suggest this analysis would be valid?

Discussion

In the discussion the authors mention about qualitative interviews. Can they clarify if this is part of this study or planned future work? If part of future plans, perhaps including a separate subsection for these would help to improve clarity to readers.

General

Is this study registered on a public database (i.e. ISRCTN or clinicaltrials.gov); if so it may be useful to include the registration number.

Level of interest

Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English

Please indicate the quality of language in the manuscript:

Acceptable
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