Reviewer’s report

Title: Intensification to injectable therapy in type 2 diabetes: mixed methods study (protocol)

Version: 0 Date: 25 Oct 2018

Reviewer: Volkert Siersma

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This paper is a protocol paper for a study about the perceptions of T2D (I got recently told that one now uses the abbreviation T2D and not T2DM anymore… personally I have no string feelings about either…) patients and primary care clinicians on initiation of injectable therapy (primarily insulin). This constitutes a considerable intensification of T2D treatment. In the paper's introduction there is made a case for starting on insulin for patients with bad glycemic control. However, given all these fine properties of injectable therapy, one wonders why delay of this therapy is a problem (especially since clinicians are nudged to initiate injectable therapy through targeted training and P4P). This is probably something that clinicians just know, but the paper should mention more explicitly some of the drawbacks of injectable therapy (I am not a clinician).

The study is characterized as a "mixed methods study", but the focus is (to me) clearly on the qualitative part. This is probably also where the expertise of the authors lies. I am a statistician, and do not know a lot of qualitative research (although I have quite some qualitative colleagues and it is contagious…). However, on the topic of planning qualitative studies, I have to point out the paper by Malterud et al 2016: Sample size in Qualitative interview studies: guided by information power, Qualitative Health Research, 26, 1753-1760 (Yes, the paper is applicable to qualitative studies broader than only interview studies, and deals with more than only sample size: it suggests some information elements to report so as others can gauge the "information power" in the study). I applaud the authors to state the number of informants to be included in the focus groups already here in the protocol paper and to avoid using the saturation principle.

On the topic of sample selection, I read that all T2D patients (adult, etc.) are eligible for interviews and focus groups, but wouldn't you want a narrower group, e.g. T2D patients that have suboptimal glycemic control and with some of them already on injectable therapy (or maybe specifically not on injectable therapy yet)?

There will be three simulated surgeries shown to the clinicians in connection with the focus groups, or are they performed by the clinicians in the focus groups? It is a bit unclear. Data will be generated in the videos of the simulated surgeries, but this is still part of the qualitative part of the study I figure. Some schematic of when and where what will take place (some timeline?) could be helpful.
The quantitative part of the study takes the form of a survey where the statements from the qualitative part are assessed by a representative sample of patients and clinicians: 40-50 participants in all (or is it 40-50 patients and 40-50 clinicians?). It is not so clear what the purpose is of this "consensus exercise". As I read it, this survey assesses the prevalence of the perceptions that correspond to the statements in the population (of patients and/or clinicians). For example, if the theme "fear of needles" appeared in the qualitative part of the study, a statement could be "I am afraid of needles" and if 40 out of 50 patients agreed with this, we could claim that this is a highly prevalent experience and worthy to take into consideration when injection therapy has to be initiated; notably because we have a representative sample. Maybe such example could be written into the paper? But what is written in the paper is that some agreement is sought and it is not clear why there should be agreement and what this will tell us. How do the authors imagine a representative sample (of patients) is gathered, and representative of what underlying population? Hence, for the quantitative part of the study I would like to see planned an analysis that assesses whether the sample can be viewed as representative, and a report of the prevalence of the generated statements (that will correspond to the themes found in the qualitative part). Here one could even do a formal power calculation to validate your "40-50": how many respondents are necessary to get a 5 percentage point error margin on the prevalence estimate? Do you think that a 9-point Likert scale is not too fine? What about a five-point scale? How many statements are you planning to put in the survey? Will there be multiple statements per theme found in the qualitative part? In summary, I had a hard time figuring out the quantitative part of the study, this has to be described clearer.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
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