Author’s response to reviews

Title: INTEGRA study protocol: Primary Care Intervention in Type 2 Diabetes Patients with Poor Glycaemic Control

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Author’s response to reviews:

Tovah Honor Aronin, Ph.D.
Editor-in-Chief
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Dear Dr. Tovah,

We are pleased to return a second revised version of the manuscript with MS Number FAMP-D-17-00014R1 entitled “INTEGRA study protocol: Primary Care Intervention in Type 2 Diabetes Patients with Poor Glycaemic Control”. We appreciate the comments provided, which again enabled us to improve the quality of our manuscript. We have attached a point-by-point response to each of the comments and noted the changes made.

We hope that the revisions in the manuscript and our accompanying responses will be sufficient to make our manuscript suitable for publication in BMC Family Practice.
Thank you for the attention to our manuscript and the interest expressed by the Reviewers.

We shall look forward to hearing from you at your earliest convenience.

Yours sincerely,

Dídac Mauricio, on behalf of all co-authors

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We appreciate the input given by the Reviewer. Below, you will find a point-by-point description of how each comment has been addressed. Original Reviewer’s comments are written in boldface, and responses in regular typeface. Please note that, in the revised version of the manuscript that we are submitting, changes are highlighted in yellow so that they can be easily tracked.

Márcio Flávio Moura de Araújo (Reviewer #1)

1. It is important that the authors justify the cutoff point for the adopted glycated hemoglobin (> 9%). I considered this cutoff point very high. Around the world, for example, the most clinical guidelines for diabetes management stipulate cutoff point (> 7%) as a negative predictor in people with diabetes. Besides that, there is a consensus (among endocrinologists and diabetologists researchers) that the change in <1% has a significant clinical and therapeutic representativeness in people with diabetes. One suggestion, if possible, would be to stratify at least two cutoff points for glycated
hemoglobin (7% and 9%, respectively). In this way, the findings presented would be more diversified and would better indicate the impact of the proposed protocol.

We thank the Reviewer for this comment. At the time of the Protocol writing, there was no consensus between different guidelines on the HbA1c cut-off at which insulin treatment should be started in type 2 diabetes. For instance, the Spanish Diabetes Society suggested that insulin should be initiated when HbA1C levels rise above of 8.5% (1), while the American Association of Clinical Endocrinologists (AACE) recommended that this should be done when HbA1C levels are above 9% (2). On the other hand, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommended that insulin should be started for patients with HbA1c values above 10% (3). At that particular moment, the participant Researchers agreed that the best definition of poor glycaemic control would be to apply the AACE definition, which corresponded to an HbA1c value in between the recommendations of different guidelines. Another reason for choosing this criterion was related with the characteristics of our population and primary health care patterns of treatment (4). Indeed, the subgroup of subjects above a HbA1c threshold (>9%) are usually those who often need to be treated with insulin, but the initiation of this therapy is frequently delayed or not even started by some general practitioners in our area. Therefore, by choosing this apparently high cut-off, we were selecting a poorly-controlled subgroup of subjects needing an intervention strategy necessarily focused on delivering the most complex available intervention that must be applicable under real clinical-practice conditions. Since we understand that the choice of the HbA1c ≥9% cut-off needs to be justified, we have added a brief paragraph on this issue in the new version of the manuscript (Discussion section; Page 24; Line 606)

“The research team agreed to define poorly controlled T2DM patients as those who had HbA1c levels ≥9%. This is because at the time of the Protocol writing, local and international guidelines were recommending the initiation of insulin therapy in type 2 diabetes when HbA1c levels were between 8.5 and 10% [33,34]. Due to this the lack of agreement, the ≥9% cut-off was chosen in accordance with the AACE Comprehensive Diabetes Management Algorithm 2013 [35], which is actually a value in between all recommendations. Moreover, our population characteristics and primary health care patterns of treatment were taken in account. Indeed, those subjects with HbA1c levels >9% are usually the ones that most often need to be treated with insulin, but this therapy is frequently delayed or not even started by some general practitioners in our primary health-care centres[4].

Reference:


2. In the Introduction, I suggest that the authors describe succinctly, in a single paragraph, the differential in their proposal from this protocol in relation to the others already presented in the background.

We thank the reviewer for this suggestion. Generally, poorly controlled DM2 patients that require intensification of their antidiabetic treatment, initiation of insulin or intensification of previous treatment with insulin are still often managed by endocrinologists. However, in the real-world clinical primary healthcare environment, these complex managements are often the main barrier for both professionals and the patients. The INTEGRA intervention addresses this issue. As suggested by the reviewer, we have added a paragraph to include this information (Background section; Page 6; Line: 184).

“Previous studies have shown that specialised Diabetes Units improve glycaemic control [14]. Our main intervention was designed to evaluate whether a local monographic consultation run by primary healthcare professionals could be effective in the context of real-world primary healthcare practice for the management of very poor controlled diabetic patients.

Reference:


3. I suggest that the authors substitute the expression blood sugar for glycemia.

Thank you for this suggestion. We have modified the manuscript accordingly (Methods section; Page7; Line 251)

…”effectiveness and cost-effectiveness in controlling glycaemia blood sugar and other metabolic and risk factor parameters compared to the usual practice”

4. Even though the qualitative phase of this research has already been published, it would be interesting to comment about the phenomenological framework adopted. Since the authors mentioned only the content analysis in this current version.

We agree with the Reviewer that this phase of the study, although already published, should be briefly commented in the current manuscript. Following the Reviewer’s suggestion, we have added a new paragraph in the Methods section to briefly describe the phenomenological framework adopted (Methods section; Page11; Line 291)

“Phase 1: Qualitative study

Design: A qualitative study with a phenomenological approach was conducted to identify the barriers and facilitators for the management of poorly controlled T2DM patients. This approach was taken in order to identify psychosocial factors influencing glycaemic control. Briefly, we collected information on the patient’s perception on the communication of the diagnosis, cognitive representation of the disease (knowledge, cause, symptoms, duration, consequences and control of the disease), emotions associated with the disease (e.g., fears or worries about the future), and their cognitive and emotional attitudes regarding strategies to control diabetes (diet, physical activity, and pharmacological activity). Finally, patients described their perceived relationship with the health-care professionals and gave their input regarding the design of the INTEGRA study (e.g., visit schedule or use of information and communication technologies). The results of this phase of the study were used to draw recommendations and to design
strategies in order to optimize the patient’s adherence and disease control during the intervention phase of the INTEGRA study.”

5. Authors need to review the final writing of the paper as well, since in some moments the verbs are in the past, and in others in the future. Before the final acceptance of this paper this item must be revised.

As suggested by the reviewer, we modified the verbal tenses throughout the manuscript according to the following rules: a) for phases already completed (i.e., the qualitative phase), with results already published, we use past tense; b) for planned but not yet accomplished objectives, the verbs are left in future tense.