Reviewer’s report

Title: Makes FLASH the difference between intervention group and treatment-as-usual group in an evaluation study of a structured education and treatment programme for flash glucose monitoring devices in people with diabetes on an intensive insulin therapy: study protocol for a randomized controlled trial

Version: 0 Date: 09 Dec 2017

Reviewer: Laura Bravo

Reviewers report:

The manuscript is well written and clearly establishes the objectives of the randomized clinical trial planned to assess the effect of educational training on an optimal utilization of the FLASH glucose monitoring system on long-term glucose control by diabetic patients.

However, there are some minor aspects that would improve the quality of the manuscript. Specially, description of the study design and procedures is not very clear. Table 1 should include the time (week of the treatment) each session will be held, since descriptions in the text are a bit confusing. The same applies to the time elapsed between each visit (1 to 4), that should be included in Figure 1. Who will be responsible for the educational program in each of the 40 clinics? Please state clearly in the text.

In page 3, line 12 it is said that "three to eight patients aged 16 to 75 years” will be the group setting as established in the protocol of the trial. Although reduced groups of 3-8 participants is positive, maybe the efficacy of the educational program would be higher if more homogeneous age groups are formed, since the form of explaining and motivating teenagers would be quite different to how to address elderly patients.

Since the FLASH system is already available, an exclusion criterion should be previous use of this monitoring system by patients.
Level of interest
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Statistical review

Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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