Reviewer’s report

Title: Patient information, communication and competence empowerment in oncology (PIKKO) – Evaluation of a supportive care intervention for overall oncological patients. Study protocol of a non-randomized controlled trial.

Version: 0 Date: 25 Feb 2020

Reviewer: Rainer Leonhart

Reviewer's report:

A very interesting project. Highly relevant, as cancer patients often have a long way to go through the medical and social services. Therefore research seems to be very necessary here.

My questions and remarks are principally related to the timing of the publication and the statistics.

If I have understood the work correctly, the ethics proposal was approved in November 2017, then the data was collected immediately. Less than a year later, in October 2018, the trial was registered. Why so much later? This would have to be justified. In my working world, after the ethics proposal, the trial is first registered and then the data collection is started. Why was there so much delay? This needs to be justified in the work.

And the study protocol is only now available in February 2020, one month before the now planned end of data collection. Why only now?

The time period for the survey of the control group and the intervention group is not identical. One year versus one and a half years. Why? Again, there are open questions for the reader.

The combination of dropout rate and imputation is also not clear to me. Alpha at .05 and beta at .10 is rather unusual. Why not both the same or beta 4 times as high? On the one hand a high dropout rate of 50% is expected for the sample calculation, on the other hand the data is not clear to me.

338 per group, that makes 676 in total and not 667 as in the text (typos?). If one assumes a dropout rate of 50% here, 676 people would have to be collected per group. This makes 1352 in total and not 1014 as described in the text. As a result, the project is overfinanced here, or the sample size was calculated incorrectly.

The statistical procedure is also not clear to me. Surveys over five measuring points: But the primary analysis is only on t2 and "only" a t-test on one variable. But the design should analyze over several measurement times and has several dependent variables. Or why else were all these measurement points and variables collected?

In my view, the study and the data set require a latent growth model. Here one could take into account several dependent variables and also introduce covariates.
The lack of randomization is not good from the evidence. A more detailed explanation would be desirable.

Overall, the study protocol leaves various questions unanswered for the reader.

**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.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
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Unable to assess

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

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