Author's response to reviews

Title: Difficulties in recruitment for a randomized controlled trial involving hysterosalpingography.

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Author's response to reviews: see over
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To the Editor-in-Chief, Dr Regina Kulier,

Re: Manuscript 1786758158934311 - Difficulties in recruitment for a randomized controlled trial involving hysterosalpingography- by DAM Perquin, AJM de Craen and FM Helmerhorst.

Dear colleague,

We would like to thank the reviewers for critically reading the manuscript and for their helpful comments. We have addressed all comments given by the reviewers and have also responded to them by inserting our answer underneath each of their remarks.

With many thanks and kind regards.

Yours sincerely,

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Reviewer 1

1. Provide rationale related to importance of documented reasons in second paragraph of background.

In the second paragraph of background we added the following sentences (in yellow):

The power of the study was based on randomization of 750 subfertile women. Recruitment of patients into the trial was more difficult than expected. **In the trial planning stage the highest recruitment rate was estimated to be from Leiden University Medical Centre based on data of the participating hospitals.** When we were halfway the trial the participating hospitals only recruited 177 women instead of the anticipated 375 women. To understand this low recruitment rate, we initiated current study to find strategies to avoid the major reasons for non-participation which could be implemented during the second half of the study or later in other studies focused on reproductive medicine. This study identifies potential eligible participants visiting one of the three participating hospitals (Leiden University Medical Centre) during the first half of the recruitment period. (Page 3)

2. The authors should present why they studied information halfway the study in one hospital.

We added the following paragraph in the discussion:

A disadvantage of our study is that we studied the major reasons of non-participation of potentially eligible participants visiting only one hospital. Unavoidable reasons of non-recruitment accounted for three quarters of the non-participation. The exclusion factor might be higher in an academic centre due to specific referrals for a tertiary university hospital. The referred subfertile couples could be older, have severe androgenic pathology or proven tubal pathology needing specialized assisted reproductive treatments. The objective of this study was to find strategies to avoid the major reasons for non-participation which could be implemented during the second half of the study or later in other studies focused on reproductive medicine. We assume that the major avoidable reasons of non-participation (like trial refusal) would be equally divided among all participating hospitals. (Page 8)

3. The authors may want to present some potential preventions for each avoidable reason.

We added the following sentences on prevention of avoidable reasons of non-recruitment in the last paragraph of the discussion:

To overcome the avoidable inattentive clinicians, attention must be paid to appropriate instruction of the study protocol to the potentially participating doctors to increase approaching of eligible patients. (Page 7)

This major avoidable patient related reason of non-participation could possibly reduced with providing adequate information on the procedure, preferably in understandable language to the patients. (Page 7)
Reviewer 2

1. Provide more detail in the method section about a) that this study includes a subsample of the total population b) recruitment method e.g. how were the potential eligible participants identified, who approached the patients, who recorded the reason for non-participation etc..

a) In the methods section we have included “during the first half of the recruitment period”. (Page 4)

b) We have added the following sentences in the method section:
Women were asked to participate in the trial by their treating gynecologist at the time that HSG would normally be planned and informed consent was obtained. If the women refused to participate in the trial, the reason for non-participation was recorded. A computer-based 1:1 ratio randomization procedure was used to allocate the women into two groups; the HSG group or the laparoscopy group. (Page 4)

2. Table 3 can be combined with table 1.
We have combined table 3 with table 1. (Page 12)

3. Give more background information on the aim of the study.
We have added the following sentence in the method section:
All women in our study participated in a multicentre randomized controlled trial with or without the performance of HSG to assess the usefulness of hysterosalpingography as routine investigation in the fertility work-up prior to laparoscopy and dye. (Page 4)