Author's response to reviews

Title: Improving patient-centredness of fertility care using a multifaceted approach: study protocol for a randomized controlled trial

Authors:

Aleida G Huppelschoten (a.huppelschoten@obgyn.umcn.nl)
Noortje TL van Duijnhoven (n.vanduijnhoven@obgyn.umcn.nl)
Rosella PMG Hermens (r.hermens@iq.umcn.nl)
Chris Verhaak (c.verhaak@mps.umcn.nl)
Jan AM Kremer (j.kremer@obgyn.umcn.nl)
Willianne LDM Nelen (w.nelen@obgyn.umcn.nl)

Version: 3 Date: 28 August 2012

Author's response to reviews: see over
Dear Editor-in-Chief,

Herewith we submit the revision of our manuscript MS: 1021955073721255 entitled 'Improving patient-centredness of fertility care using a multifaceted approach: study protocol for a randomized controlled trial'. We are grateful that you recommended publication and hope that formal acceptance will be given after the minor revisions we carried out.

We made revisions according to your valuable suggestions and of the reviewer. These revisions are visible in the highlighted manuscript as the coloured text. In the addendum, you will find the comments of the reviewer listed in bold, with our answers point by point below.

We hope that our revisions have sufficiently answered the expectations. If you need any further information, please do not hesitate to contact us.

Sincerely yours,

W.L.D.M. Nelen, MD, PhD and A.G. Huppelschoten, MD
Comments reviewer

1. Please explain “QoL” when used for the first time.
   We regret that we did not explained the term ‘quality of life’ (QoL) in our manuscript when we used this term for the first time, i.e. in the abstract section. We revised this sentence, making it clear to the reader what is meant with ‘QoL’.
   (Revised version: line 34)

2. Background, p. 4, line 89-90.
   The author states that infertility affects 9-15 % of the childbearing population when referring to Boivin et al., 2007. However, the infertility estimates in this publication by Boivin et al. are based on population studies also including women/couples who have not (yet) tried to become parents. To my opinion it would probably be more relevant to present the estimate of lifetime prevalence of infertility among those women/couples who have tried to achieve parenthood; in this case the lifetime prevalence of infertility in population-based studies from developed countries varies from 16-28 %. Alternatively, keep the reference to Boivin et al. and clearly explain that these infertility estimates are based on studies including women in certain age groups irrespectively whether they have tried to become mothers or not.
   This is a valuable suggestion of the reviewer. We agree that it is more relevant to present the lifetime prevalence of infertility among those who have actually tried to become parents. Therefore, we revised this part of the paper and included the prevalence numbers from two clinical reviews of Schmidt (Hum Reprod, 1995) and Taylor (BMJ, 2003).
   (Revised version: lines 89-90, 406)

3. Background, p.4, line 89.
   The author states that infertility is an “increasing medical problem”. Very few studies have conducted repeated measurements of the infertility prevalence in a population in identical geographical regions over time. These studies report conflicting results – indicating either no changes in infertility prevalence or a slight prevalence increase in younger cohorts. There is no doubt that the number of fertility patients increase across all countries – but I will recommend not to state that infertility in itself yet has increased.
   The reviewer is absolutely right that no literature exists about the fluctuation of the prevalence of infertility over time. Therefore, we removed the statement ‘infertility is an increasing medical problem’. We consider that no replacement of this sentence is necessary, as we already provided the percentages of patients suffering from infertility. This statement informs the reader about the magnitude of fertility problems in developed countries already.
   (Revised version: line 89)

4. I am aware that the concept “dropout” is frequently used when patients terminate treatment while treatment options – from a medical stand point – still exists. However, studies have shown that patients have several reasons for deciding to terminate treatment before all treatments options have been used. Furthermore, that early treatment termination often is a serious process involving negotiation between the partners and frequently also fertility clinic staff. In respect for the fertility patients and the process leading to early treatment termination I find it more appropriate to label this as e.g. decision-making about early treatment termination instead of characterizing it as “dropout”.
   We agree with the reviewer that discontinuing fertility treatment is a process in which both the professional and the patient have a significant role. We support the suggestion to replace the term ‘dropout’ and use some milder terminology such as ‘decision-making about early treatment termination’. Throughout the paper, we applied this adapted formulation of patients discontinuing fertility treatment.
   (Revised version: lines 101-102, 120-121, 337-338)
5. **Background, p. 4, line 89.**

   The author describes infertility as a “medical problem” and not as a reproductive disease. Probably it could be relevant to adhere to the revised ICMART and WHO terminology where infertility is defined as “a disease of the reproductive system ....” (Zegers-Hochschild *et al.*, Human Reproduction, 2009).

   We kindly refer the reviewer to the answer on comment 3. In this section we explained why we removed the words ‘increasing medical problem’ in our paper. Therefore, it is not possible anymore to fulfill this proposed revision, although we do agree with the reviewer on the comment she made.

6. **A question**

   The authors have planned to use the SCREENIVF questionnaire to measure the emotional adjustment. To the best of my knowledge this instrument is developed to screen women in ART treatment. Has this instrument now been tested among men as well? We know from a large number of studies that women and men frequently report the emotional consequences of infertility and treatment differently.

   Thank you for this interesting and valuable question. Indeed, the SCREENIVF questionnaire is validated in women only, but it would be interesting to explore the SCREENIVF results of both women and partners, as they are both part of the infertile couple. Therefore, we are conducting a separate study to compare risk factors for emotional maladjustment (SCREENIVF) between women and their partners. Our aim is to publish these results in a short communication next year.

   **Comment editor-in-chief**

1. **Please remove the conclusion section of your manuscript. This section is not needed in protocol articles.**

   As requested by the editor-in-chief, we removed the conclusion section of our manuscript.