Author's response to reviews

Title: The PRCI study: Design of a Randomized Clinical Trial to evaluate a coping intervention for medical waiting periods used by women undergoing a fertility treatment

Authors:

Henrietta D.L. Ockhuijsen (h.d.l.ockhuysen@umcutrecht.nl)
Agnes van den Hoogen (ahoogen@umcutrecht.nl)
Nickolas S Macklon (N.S.Macklon@soton.ac.uk)
Jacky Boivin (boivin@Cardiff.ac.uk)

Version: 3 Date: 8 August 2013

Author's response to reviews: see over
Dear Dr Peter O'Donovan,

Thank you very much for the comments on our manuscript entitled: “The PRCI study: Design of a Randomized Clinical Trial to evaluate a coping intervention for medical waiting periods used by women undergoing a fertility treatment” by H Ockhuijsen, A van den Hoogen, N Macklon and J Boivin, for publication in BMC Women’s Health.

The comments of the editor and reviewers were very helpful in further improving our manuscript.

We have carefully studied the comments and included a point-by-point summary of our response on the comments (see below).

Sincerely yours,

Henrietta DL Ockhuijsen, MSc, RN
Nurse Researcher
Department of Reproductive Medicine and Gynaecology, University Medical Center Utrecht,
Room C05.2.18
PO Box 85500
3508 GA Utrecht, the Netherlands
Tel +31 88 755 3628
h.d.l.ockhuysen@umcutrecht.nl
Answer to the comments of the referees:

Abstract: please clarify the four arms more specific. You write three-armed however in the manuscript you have added one more group= four armed.

- Thank you for this comment. We added the fourth non randomized group in the abstract.

There are a lot of instruments to choose between regarding anxiety. If anxiety is the primary outcome, why do you not use a more specific instrument for anxiety (STAI for example)?

- The reason that we have not used the STAI is because we also intent to validate the questionnaire SCREENIVF. The SCREENIVF has items from the STAI. This is the reason why we used the HADS instead.

Method: Please refer to Table I. It is good that you can follow the reasons for having four group however it is a little confusing to understand the differences without having Table I in front of you.

- Agree and added table 1 in the text of the method section.

Sample size: To test the difference in psychological wellbeing.........You should may be calculate on your primary outcome= anxiety / HAD.

- Agree, psychological wellbeing is to general. Changed this into anxiety..

Randomization: What happen if the patients do contact you/staff during the waiting period?

- Good point. The staff is blinded for the randomization of the patients. So when patients contact the staff during the waiting period (from experience we know that it does not happen very often) they will treat all patients the same way as instructed and according to the protocol.

Figure 1 flow chart: Add in the chart the assessments T1, T2 and T3 as well to make the points for assessments clear.

- We have added time points to the flow chart.

Figure 3 not important

- Deleted figure 3
Introduction.
1. The background information in general is informative. However there are some issues that have not been mentioned. The authors should include some information about the possible consequences of infertility related stress (e.g. reduction in pregnancy rates, there are many primary studies and some systematic reviews that have explored the impact of stress on IVF outcome) in order to demonstrate the necessity of offering an intervention.

Methods

- Thank you for this comment. We added more detailed information in the background.

2.1. Do midwives work in fertility clinics in the Netherlands? If yes, this should be referred in the study protocol. By this way the international readership will be able to know what type of personnel can offer fertility support in the Netherlands.

- Midwives are not working in our department.

2.2. It should be specified which program was used for the sample size calculation.

- We did not used a program instead we used tables in the book of Polit and Hungler. See references.

2.3. The authors should specify what are they planning to do with not normally distributed data. It is very possible to have some variables with not normally distributed data. They can either use non parametric statistical tests and these tests should be specified or they can make mathematical transformations for normalizing the data. I think that these should be specified in the section of data analysis.

- We added the next sentence: If study variables are not normally distributed then data will be transformed to normalise (e.g., square root, log, etc as is required).