Letter to the Editor



ARTICLE HISTORY: Received 18 January 2022/Published Online 27 April 2022

To the Editors,

Koumparou et al¹ recently published a randomized controlled trial (RCT) on the effectiveness of psychological interventions (stress management training, SMT) for women planning *in vitro* fertilization (IVF). They concluded that while the effect of SMT was limited in terms of IVF outcome, it resulted in a significant reduction of stress levels in infertile patients. Since most women undergoing infertility treatment are exposed to high psychological stress,² this study may be of great value in demonstrating the need for proactive SMT to maintain infertile women's mental health and motivation to continue treatment. However, we are concerned that the reliability of this RCT has been compromised in several ways.

First, the registration of the RCT was not clearly stated. According to The CONsolidated Standards of Reporting Trials (CONSORT) 2010 guidelines, a prospective registration of the RCT is required, which prevents unnecessary concerns about the bias of results selection.^{3,4}

Second, the lack of specific figures on the background of the participants in the case and control groups risks distorting the RCT results. The article states that there was no significant difference between the two groups. However, since aging and prolonged infertility treatment increase the psychological burden on infertile patients,⁵ detailed background information is necessary to interpret the results of an RCT accurately. Selection bias could not be determined, which weakened the validity of this RCT.

Furthermore, the absence of any mention of case dropout makes the conclusions of this RCT uncertain; a discussion of cases demonstrating difficulty in completing an 8-week psychological program would clarify whether temporary SMT would show efficacy for patients.

Finally, it is essential to note that the details of IVF have not been clarified. Since the timing of the SMT and IVF-ET cycles or details of the IVF-ET protocol were not shown, this RCT could not be used as a reference for IVF facilities to actually operate SMT. There is no doubt that psychological interventions are necessary for infertile patients exposed to high psychological stress, but this RCT has many details that have not been clarified and the conclusions are attenuated. As details become clearer, this RCT will provide a foundation for the active use of SMT in infertility treatment settings.

Acknowledgments. We would like to thank Editage (http://www.editage.jp) for English language editing.

Shinnosuke Komiya

Department of Obstetrics and Gynecology, Kansai Medical University Graduate School of Medicine, Osaka, JAPAN, HORAC Grand Front Osaka Clinic, Kita-ku, Osaka, JAPAN, e-mail: komiya0703@gmail.com

Masahiro Banno

Department of Psychiatry, Seichiryo Hospital, Nagoya, JAPAN, Department of Psychiatry, Nagoya University Graduate School of Medicine, Nagoya, JAPAN, Scientific Research WorkS Peer Support Group (SRWS-PSG), Osaka, JAPAN

Yuki Itagaki

Department of Surgery, Japanese Red Cross Asahikawa Hospital, Hokkaido, JAPAN, Scientific Research WorkS Peer Support Group (SRWS-PSG), Osaka, JAPAN

References

- 1. Koumparou M, Bakas P, Pantos K, Economou M, Chrousos G. Stress management and *In Vitro* Fertilization (IVF): A pilot randomized controlled trial. *Psychiatriki* 2021, 32:290–299, doi: 10.22365/jpsych. 2021.029
- Volgsten H, Svanberg AS, Olsson P. Unresolved grief in women and men in Sweden three years after undergoing unsuccessful in vitro fertilization treatment. Acta Obstet Gynecol Scand 2010, 89:1290–1297, doi: 10.3109/00016349.2010.512063
- 3. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010, 23, 340:c869, doi: 10.1136/bmj.c869
- 4. Page M, Boutron I. RoB 2 Domain 5: bias in selection of the reported result. Available from: https://training.cochrane.org/resource/rob-2-domain-5-bias-selection-reported-result. Accessed 12 Jan 2022
- Gonda KJ, Domar AD, Gleicher N, Marrs RP. Insights from clinical experience in treating IVF poor responders. *Reprod Biomed Online* 2018,36:12-19, doi: 10.1016/j.rbmo.2017.09.016