



Letter to the editor: The extended pessary interval for care (EPIC) study: a failed randomized clinical trial

Fatemeh Azarkish¹ · Rokhsana Janghorban²

Received: 11 May 2021 / Accepted: 4 June 2021 / Published online: 30 June 2021
© The International Urogynecological Association 2021

We read with great interest the recent original article entitled “The extended pessary interval for care (EPIC) study: a failed randomized clinical trial” Written by Anglim et al. [1]. We congratulate the authors for their interesting study that described study design flaws and limited outcomes of a randomized trial that intended to compare satisfaction and complication rates between patients managing their pelvic organ prolapse with a pessary at different maintenance intervals. Although they approached a very pertinent topic in a scientific manner, we want the authors to pay attention to some issues. It was better that patients’ self-care was not excluded [2] and self-care was considered as a interfering variable and random allocation of patients would reduce the bias. One reason for not achieving sufficient sample size is the omission of these individuals. It was better to check the questionnaire in terms of validity and reliability and to give it to patients in a pilot study [3]. If the pilot study

had been done [4], the challenges and problems would have been identified and you would not have had to complete the research without achieving the desired sample size. There was a missing Data therefore it need to consider “intention to treatment”. Finally, by implementing all of the items listed above, extending the study interval to achieve the desired sample size would be helpful.

Author Contributions F Azarkish: manuscript writing/editing? R Janghorban: manuscript writing/editing

Compliance with Ethical Standards

Competing interests The authors declare that they have no conflict of interest.

References

1. Anglim B, Zhao ZY, Lovatsis D, McDermott CD. The extended pessary interval for care (EPIC) study: a failed randomized clinical trial. *Int Urogynecol J.* 2021;32:937–44.
2. Sioutis D, Kearney R. Use of Pessaries for Pelvic Organ Prolapse. In: *Pelvic Floor Disorders.* Springer; 2021. p. 667–73.
3. Holubyeva A, Rimpel K, Blakey-Cheung S, Finamore PS, O’Shaughnessy DL. Rates of Pessary Self-Care and the Characteristics of Patients Who Perform it. *Female Pelvic Med Reconstr Surg.* 2021;27:214–6.
4. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *bmj.* 2016;355.

Publisher’s note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

✉ Rokhsana Janghorban
Janghorban@sums.ac.ir

Fatemeh Azarkish
dr.azarkish@irshums.ac.ir

¹ Tropical and Communicable Diseases Research Center, Department of Midwifery, Iranshahr University of Medical Sciences, Iranshahr, Iran

² Department of Midwifery, School of Nursing and Midwifery, Maternal–Fetal Medicine Research Center, Shiraz University of Medical Sciences, Shiraz, Iran