Einladung zum Biometrischen Kolloquium

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INTRODUCING THE ADAPTIVE DESIGNS CONSORT EXTENSION (ACE) STATEMENT TO IMPROVE REPORTING OF RANDOMISED TRIALS THAT USE AN ADAPTIVE DESIGN

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Besprechungszimmer Institut für Medizinische Statistik, Raumnr. 88.03.506

Medizinischen Universität Wien, Spitalgasse 23, 1090 Wien

HOST: Franz König

ABSTRACT:

The reporting of adaptive designs (ADs) in randomised trials is inconsistent and needs improving [1–5]. Incompletely reported AD randomised trials are difficult to reproduce and are hard to interpret and synthesise. This consequently hampers their ability to inform practice as well as future research and contributes to research waste. Better transparency and adequate reporting will enable the potential benefits of ADs to be realised.

We developed an Adaptive designs CONSORT Extension (ACE) guideline through a two-stage Delphi process with input from multidisciplinary key stakeholders in clinical trials research in the public and private sectors from 21 countries, followed by a consensus meeting [6]. Delphi survey response rates were 94/143 (66%), 114/156 (73%), and 79/143 (55%) in round one, two and across both rounds, respectively. Members of the CONSORT Group were involved during the development process.

The resultant ACE checklist is comprised of seven new items, nine modified items, six unchanged items for which additional explanatory text clarifies further considerations for ADs, and 20 unchanged items not requiring further explanatory text. The ACE abstract checklist has one new item, one modified item, one unchanged item with additional explanatory text for ADs, and 15 unchanged items not requiring further explanatory text. This talk will summarise the development process and introduce the ACE reporting guideline focusing on new and modified reporting items.

The intention is to enhance transparency and improve reporting of AD randomised trials to improve the interpretability of their results and reproducibility of their methods, results and inference. We also hope indirectly to facilitate the much-needed knowledge transfer of innovative trial designs to maximise their potential benefits.

References

1. Dimairo M, Todd S, Julious S, et al. ACE Project Protocol Version 2.3: Development of a CONSORT Extension for adaptive clinical trials. The EQUATOR Network. http://www.equator-network.org/wp-content/uploads/2017/12/ACE-Project-Protocol-v2.3.pdf. Published 2016. Accessed January 25, 2018.

2. Stevely A, Dimairo M, Todd S, et al. An Investigation of the Shortcomings of the CONSORT 2010 Statement for the Reporting of Group Sequential Randomised Controlled Trials: A Methodological Systematic Review. *PLoS One*. 2015;10(11):e0141104. doi:10.1371/journal.pone.0141104

3. Hatfield I, Allison A, Flight L, Julious SA, Dimairo M. Adaptive designs undertaken in clinical research: a review of registered clinical trials. *Trials*. 2016;17(1):150. doi:10.1186/s13063-016-1273-9

4. Yang X, Thompson L, Chu J, et al. Adaptive Design Practice at the Center for Devices and Radiological Health (CDRH), January 2007 to May 2013. *Ther Innov Regul Sci*. 2016;50(6):710-717. doi:10.1177/2168479016656027

5. Bauer P, Einfalt J. Application of Adaptive Designs – a Review. *Biometrical J*. 2006;48(4):493-506. doi:10.1002/bimj.200510204

6. Dimairo M, Coates E, Pallmann P, et al. Development process of a consensus-driven CONSORT extension for randomised trials using an adaptive design. *BMC Med*. 2018;16(1):210. doi:10.1186/s12916-018-1196-2

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