

Final report for HTMR project N90 - Developing CONSORT guidance for adaptive clinical trials

Applicants

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Budget - £13230

Summary of original objectives

This project was done in parallel with a NIHR CTU support grant led by Munya Dimairo. The overarching aim of both grants was to create and disseminate a CONSORT extension for adaptive clinical trials. The NIHR grant supported developing and conducting a two-stage delphi survey to identify items that should be added, modified and deleted from the original CONSORT checklist for the extension. The objectives of this project were:

- 1) Following on from the Delphi process, conduct a consensus workshop bringing together UK and international experts in adaptive design to decide on the extension.
- 2) Disseminate the CONSORT extension through conducting a workshop and presentation of the checklist at a clinical trials conference.

What was achieved/outputs

- 1) Between April 2017 and October 2017, following the two-stage Delphi process, the potential items for the CONSORT extension were developed. A one-day consensus meeting, with independent chair Professor Deborah Ashby, was conducted in November 2017. The HTMR funding allowed attendance of several international experts: Toshimitsu Hamasaki (Japan), Yannis Jemai (US), Franz Koenig (Austria), Marc Walton (US).
- 2) In February 2018 the extension was finalised and drafting of the elaboration and explanation (E&E) paper started. This paper is currently on its second complete draft.
- 3) A first paper[1] describing the process of developing the extension checklist was drafted and published in BMC Medicine during December 2018. This is also accessible via the EQUATOR network database together with the protocol. A summary NIHR report is also publicly accessible (https://www.nihr.ac.uk/research-and-impact/Dev%20of%20Adaptive%20designs%20CONSORT%20Ext_FinalReport.pdf)

- 4) Presentations about the extension have been given at ISBS 2017, GFBR LMIC 2017, Evidence Live 2017, SCT 2018, and at a meeting at the Academy of Medical Sciences on adaptive designs in January 2019.
- 5) MD and TJ, along with others, also identified the need for practical educational material on adaptive trials and successfully acquired funding from NIHR CTU support funding call to develop an online educational platform (see <https://www.sheffield.ac.uk/scharr/sections/dts/ctru/panda>).

Next Steps

- 1) We will complete the E&E paper and submit it for co-publication in BMJ and Trials in by April. Editors at BMJ have expressed a strong interest in publishing this.
- 2) We will conduct the dissemination workshop, which is scheduled for 12th June 2019. Further dissemination activities are planned following the dissemination workshop.
- 3) During the consensus meeting, a methodological gap was identified: how to best report results of interim analyses in an easy to understand, efficient way. We will discuss whether (and if so, how) to take this forward in a forthcoming planned meeting of the HTMR adaptive designs working group.

References

- 1 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**:210. doi:10.1186/s12916-018-1196-2