Investigation of the shortcomings of the CONSORT 2010 statement for the reporting of group sequential randomised controlled trials

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Outline

- ❑ Rationale for the investigation
- ❑ Addressing research questions
- ❑ Results
- ❑ Conclusion and recommendations
- ❑ Acknowledgements and references

Rationale for the investigation …

- Adaptive designs are underused
- Recent research uncovered some concerns among key stakeholders (Dimairo et al, 2015)
- Could this be linked to the reporting of the conduct of adaptive trials?
- What is the current state of reporting the most common used adaptive design?

Addressing the research question …

- Methodological systematic review
  - Parallel group and confirmatory GS RCTs (2001 to 23rd Sept 2014)
  - Free text search of terms associated with GS methods via Ovid MEDLINE
  - Two independent reviewers examined compliance in reporting
  - Reporting compliance classification system
  - Used ‘all’ accessible trial related publications to assess compliance, such as protocols and prior publications

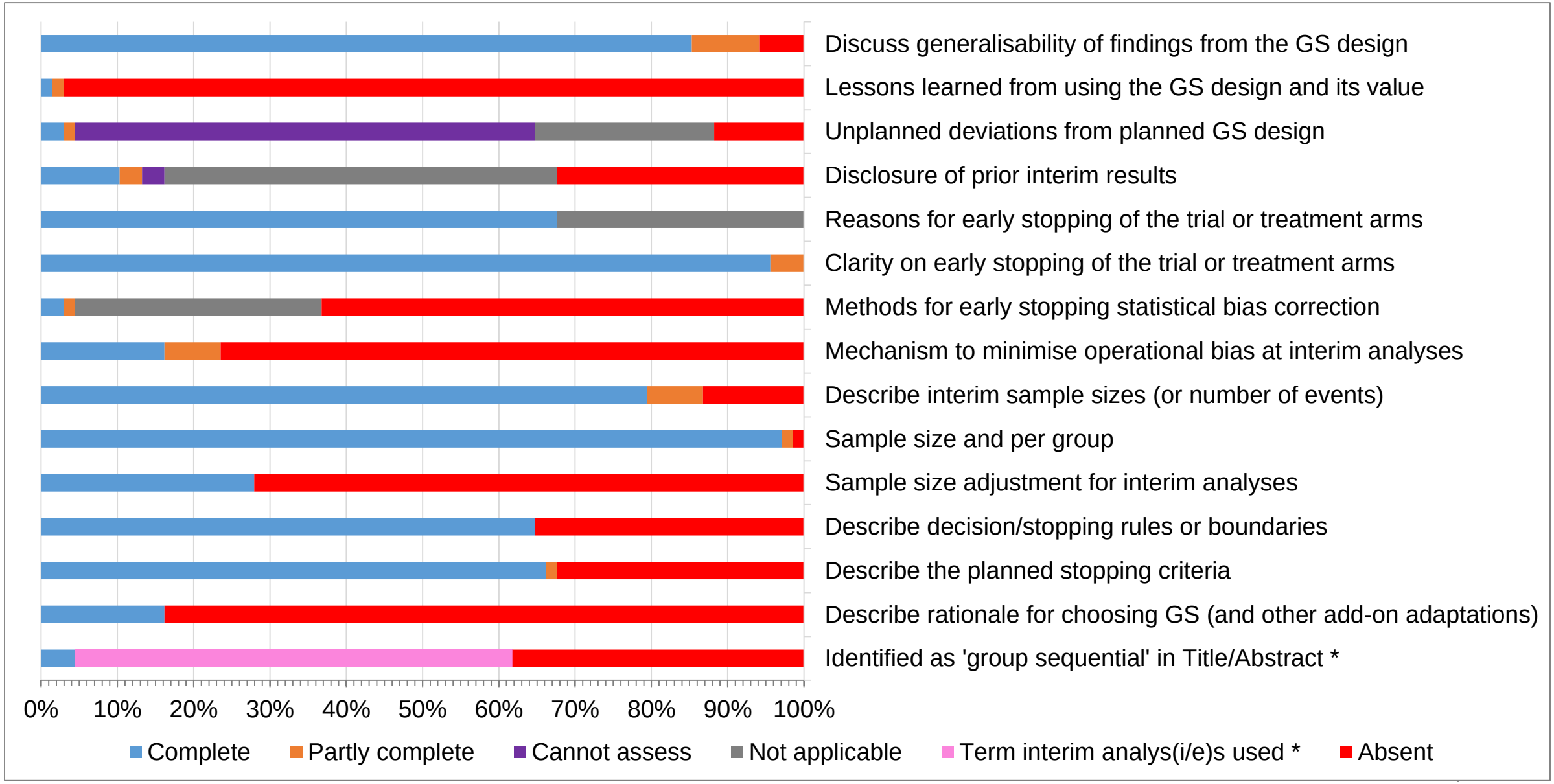
Results(1): Characteristics of reviewed trials

- 68/284 (24%) were eligible GS RCTs
- The majority were published in ‘high impact’ journals
  - Median (IQR) IF was 17.5 (6.6 to 30.4), with a max of 54 (2013 to 2014)
- 76% were in oncology
- 91% investigating pharmacological interventions
- 68% publishing journals endorsed the CONSORT statement
- 46(68%) were stopped early: 28 futility, 10 efficacy, …

Results(2): Reporting compliance to CONSORT checklist

- Most items were better reported: median(IQR);
  - '*complete*' compliance of 81% (53% to 91%), with min of 12%
  - '*at least partially complete*' compliance of 93% (78% to 97%), with min of 22%
- HOWEVER, suboptimal reporting of items relating to:
  - Methods used to generate the randomisation list(s) (47%),
  - Details of randomisation concealment (74%),
  - Implementation of randomisation (59%),
  - Details of additional analysis (43%),
  - Disclosure of trial registration information (38%),
  - Disclosure and access to full trial protocols (53%).

Results(3): Reporting compliance of GS specific aspects



Conclusions and Recommendations

- Poor reporting of group sequential specific aspects
- Assurance of scientific rigour through transparent adequate reporting is paramount to the credibility of findings from adaptive trials
- Case studies of adaptive designs are only useful when adequately reported
- Urgent need for a CONSORT extension tailored for adaptive designs in general

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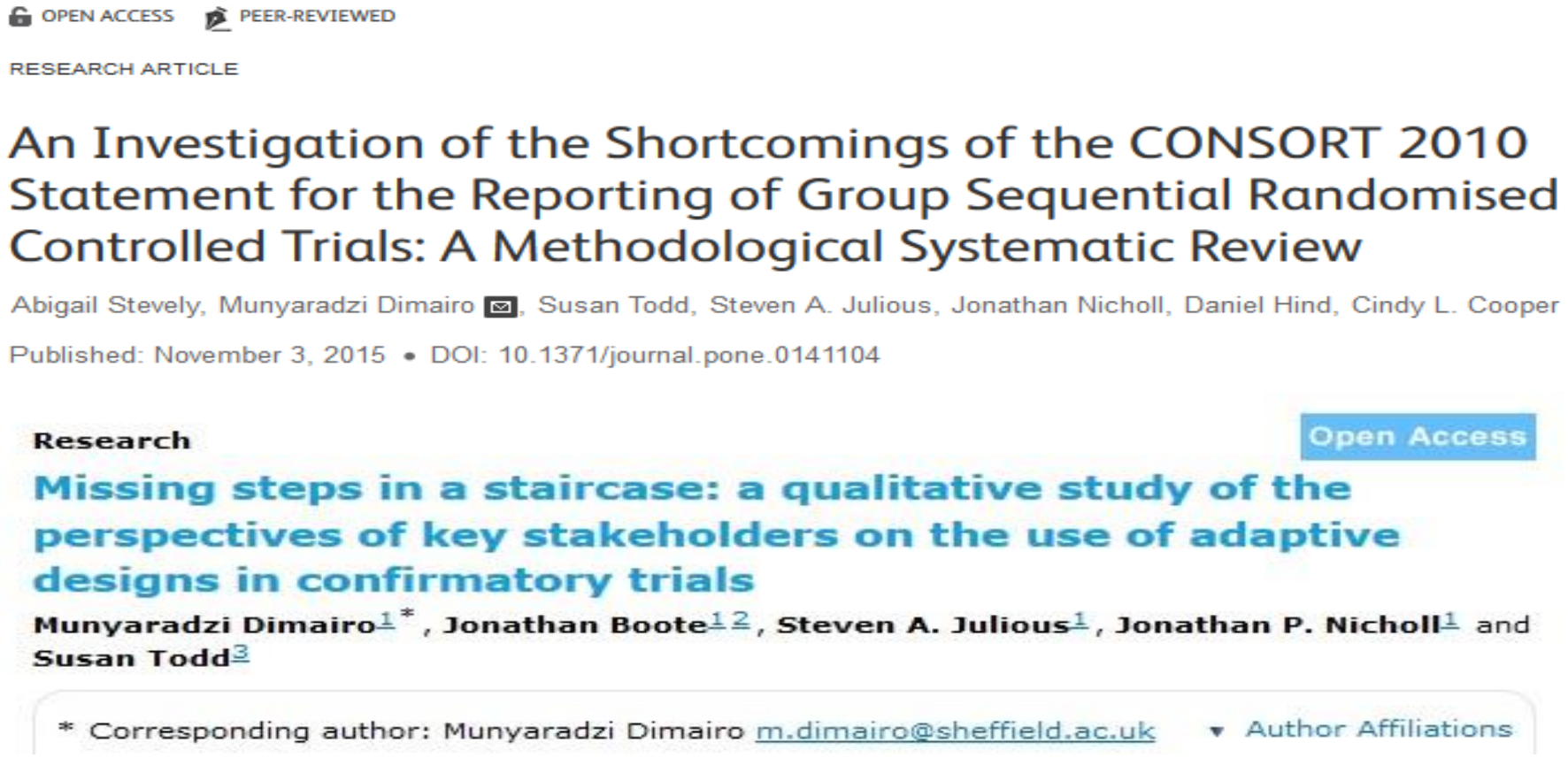
References



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RESEARCH ARTICLE

An Investigation of the Shortcomings of the CONSORT 2010 Statement for the Reporting of Group Sequential Randomised Controlled Trials: A Methodological Systematic Review

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Research

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Missing steps in a staircase: a qualitative study of the perspectives of key stakeholders on the use of adaptive designs in confirmatory trials

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Detry M, Lewis R, Broglio K et al (2012) Standards for the Design, Conduct, and Evaluation of Adaptive Randomized Clinical Trials