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## **Professional medical writing support improves the quality of reporting of randomized controlled trials**

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# Disclosures

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- Study funded by Oxford PharmaGenesis
- W Gattrell, K Young, P Farrow, R White and C Winchester are employees of Oxford PharmaGenesis, and W Gattrell, P Farrow, R White and C Winchester are shareholders
- S Hopewell is a member of the Consolidated Standards of Reporting Trials (CONSORT) group
- S Lang is a former employee of Oxford PharmaGenesis
- E Wager is the owner of Sideview, which provides training and consultancy in medical writing

## Our industry bodies say ...

“Involving medical writers may therefore raise the standard of publications and accelerate the writing and publication process”<sup>1</sup>



“... medical writers can often improve the efficiency and effectiveness of manuscript preparation by working with the research team to develop clear and concise manuscripts in a timely fashion”<sup>2</sup>

... but is there any evidence to support these statements?

## Currently available evidence

“When professional medical writers help authors prepare manuscripts, these manuscripts are less likely to be retracted for misconduct,<sup>22</sup> are more compliant with best-practice reporting guidelines,<sup>23</sup> and are accepted more quickly for publication<sup>24</sup>”

Woolley KL *et al.* Poor compliance with reporting research results – we know it’s a problem ... how do we fix it? *Curr Med Res Opin* 2012;28:1857–60

22. Woolley KL *et al.* Lack of involvement of medical writers and the pharmaceutical industry in publications retracted for misconduct: a systematic, controlled, retrospective study. *Curr Med Res Opin* 2011;27:1175–82

23. Jacobs A. Adherence to the CONSORT guideline in papers written by professional medical writers. *The Write Stuff* 2010;19:196–200

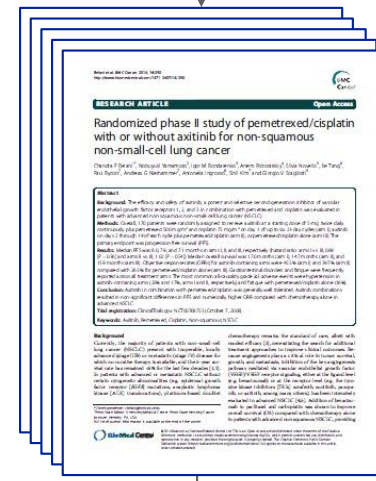
24. Bailey M. Science editing and its effect on manuscript acceptance time. *AMWA Journal* 2011;26:147–52

# Identification and review of articles

**With acknowledged medical writing support (n = 110)**

BioMed Central articles describing RCTs

277 peer-reviewed, open access journals  
**Without acknowledged medical writing support, random subset (n = 123)**



**Is there a difference?**

RCT, randomized controlled trial

1. Jacobs A. *The Write Stuff* 2010;19:196–200; 2. Hopewell S et al. *BMJ* 2010;340:c723

# Higher rate of reporting of CONSORT items with medical writing support...

## CONSORT item (number)

Pre-defined primary outcome (6a)

How sample size was determined (7a)

Method used to generate random allocation (8a)

Type of randomization (8b)

Mechanism to implement random allocation sequence (9)

Who generated the allocation sequence (10)

Who was blinded (11a)

Description of similarity of interventions (11b)

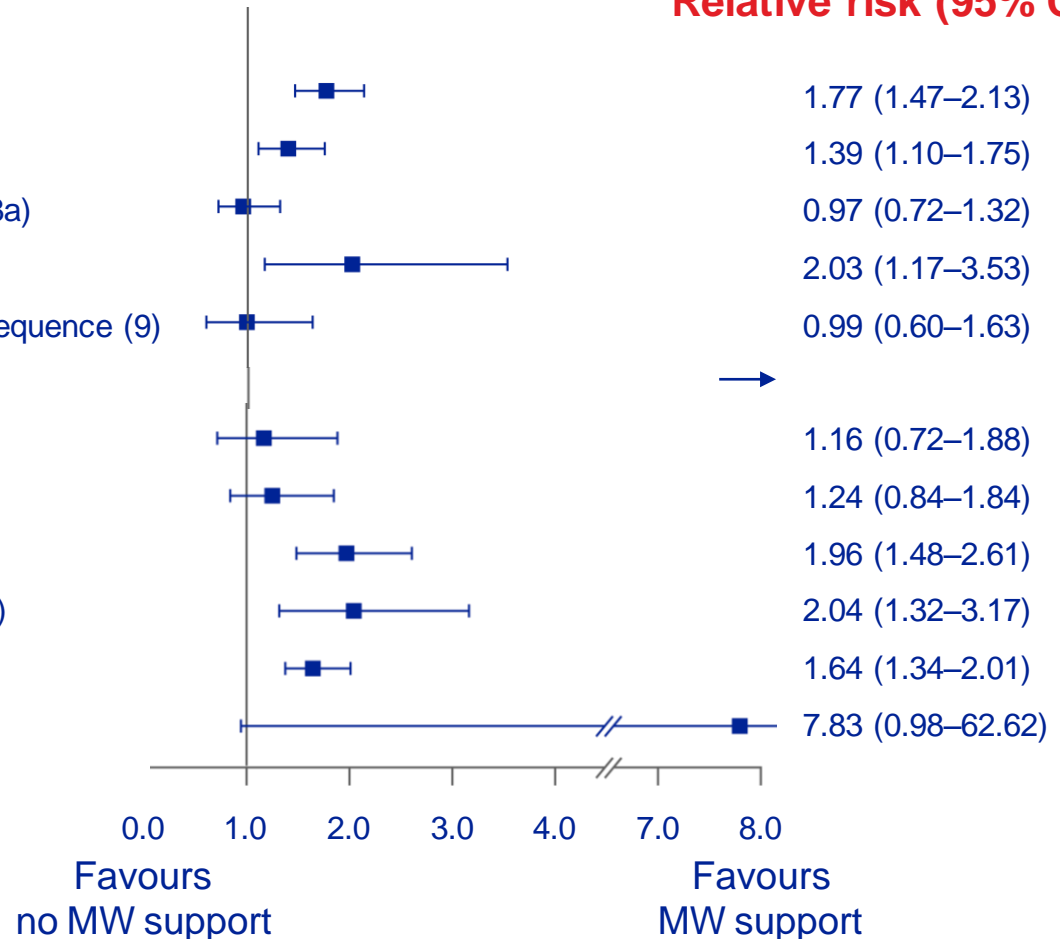
Participant flow diagram (13)

Dates defining recruitment and follow-up (14a)

Trial registration (23)

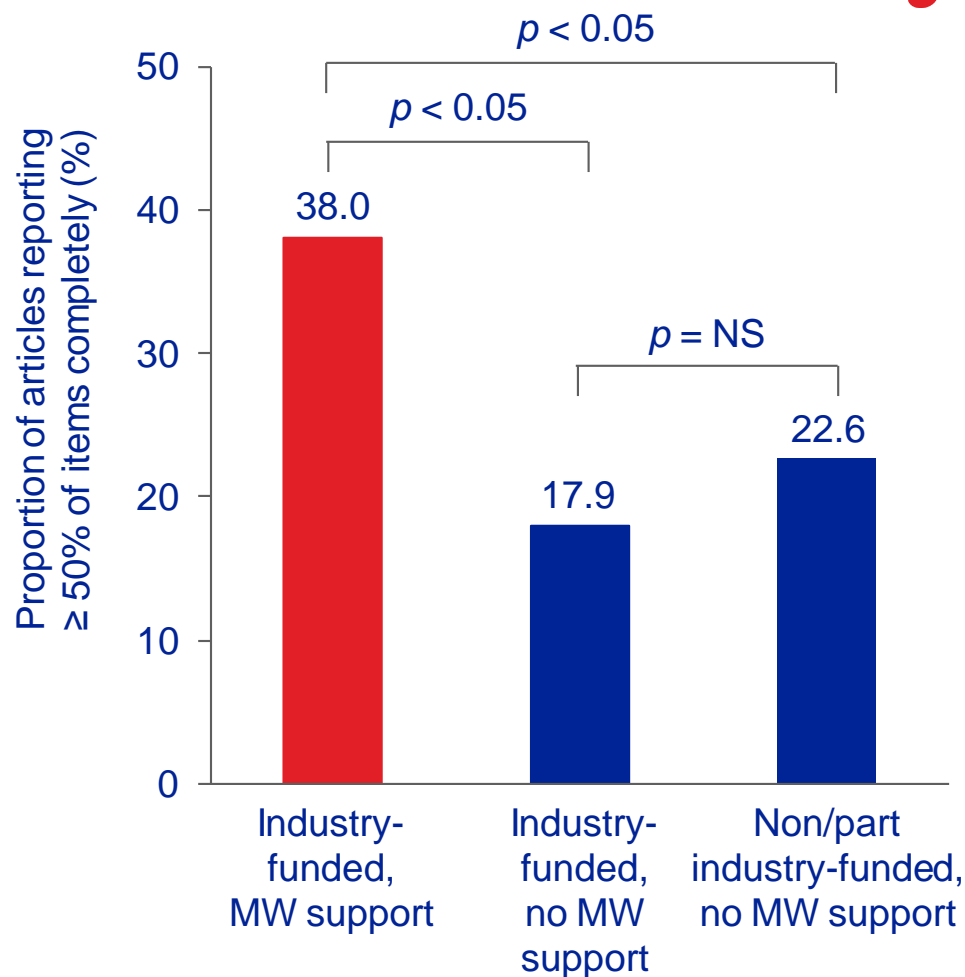
Access to study protocol (24)

## Relative risk (95% CI)



**Items were chosen that are often poorly reported**

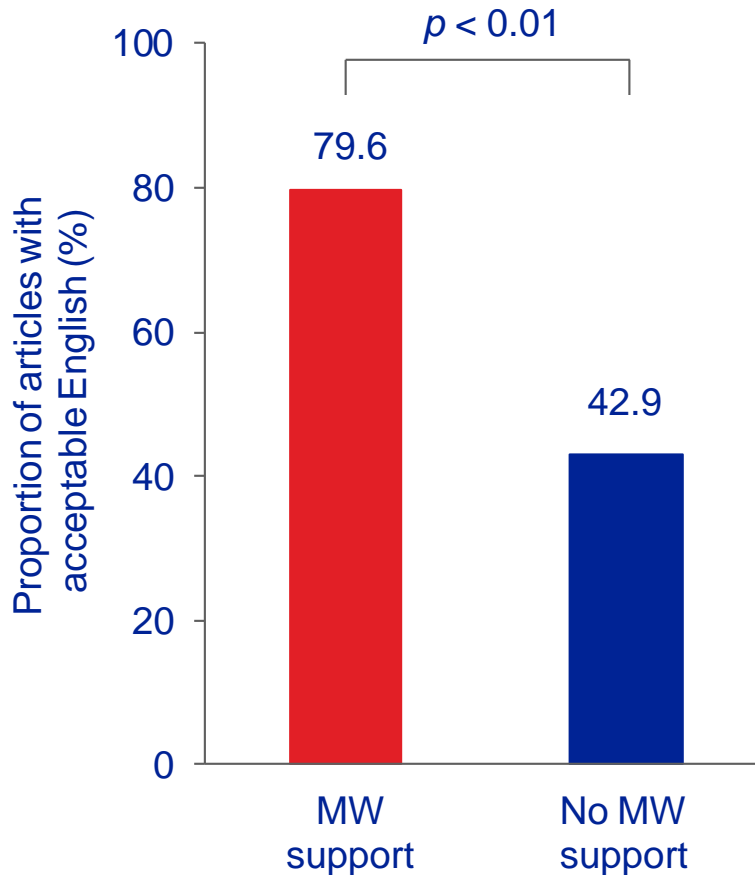
## ...irrespective of funding source



- Medical writing support was associated with enhanced reporting of CONSORT checklist items ( $\geq 50\%$ ) versus no medical writing support
- Irrespective of industry funding



# Improved quality of written English but not speed of acceptance



- Medical writing support was associated with significantly better written English, as judged by peer reviewers
  - Acceptable
  - Needs some language corrections before being published
  - Not suitable for publication unless extensively revised
- Median time from submission to acceptance was longer for supported articles than for non-supported articles
  - 23.9 versus 19.4 weeks ( $p < 0.01$ )

# Conclusions

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- Declared medical writing support was associated with higher quality reporting of RCTs in articles, compared with no writing support
  - Differences between the study groups, such as differences in funding source and publication year, do not explain our findings
- First study to demonstrate convincingly the value of medical writing support
- Further analyses to understand reason for longer median time from submission to acceptance
- Next step: full manuscript in development



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