

Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study

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Christopher Winchester

MedComms Networking Event 4 May 2016

Paul Farrow DPhil CMPP

- Communications Director at Oxford PharmaGenesis
 - More than 10 years of experience in medical communications
 - Contract Global Publications Lead for a top-10 pharma company
 - Head of the PharmaGenesis Publications Ethics, Planning and Research group
 - GPP3 reviewer
 - Guest lecturer on GPP at the University of Oxford, UK



Medical writing is misunderstood and sometimes gets bad press



The screenshot shows the top navigation bar of The Guardian website with links for 'sign in', 'subscribe', 'search', 'jobs', 'dating', 'more', and 'UK edition'. The main navigation bar includes categories like 'UK', 'world', 'sport', 'football', 'opinion', 'culture', 'economy', 'lifestyle', 'fashion', 'environment', 'tech', 'money', and 'travel'. The article title is 'Medical ghostwriters who build a brand' by Ben Goldacre, with a sub-headline 'Peer review and scientific publishing' and a note 'Comment is free'. A photo of Ben Goldacre is visible on the right. A blue banner at the bottom of the article reads 'There are no rules against this, just traditions, good faith, and leaky regulations'. The date and time 'Saturday 18 September 2010 09.00 BST' are shown at the bottom left.

Our industry bodies say ...

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



“... 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”²

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

Available evidence

“When professional medical writers help authors prepare manuscripts, these manuscripts are less likely to be retracted for misconduct,²² are more compliant with best-practice reporting guidelines,²³ and are accepted more quickly for publication²⁴”

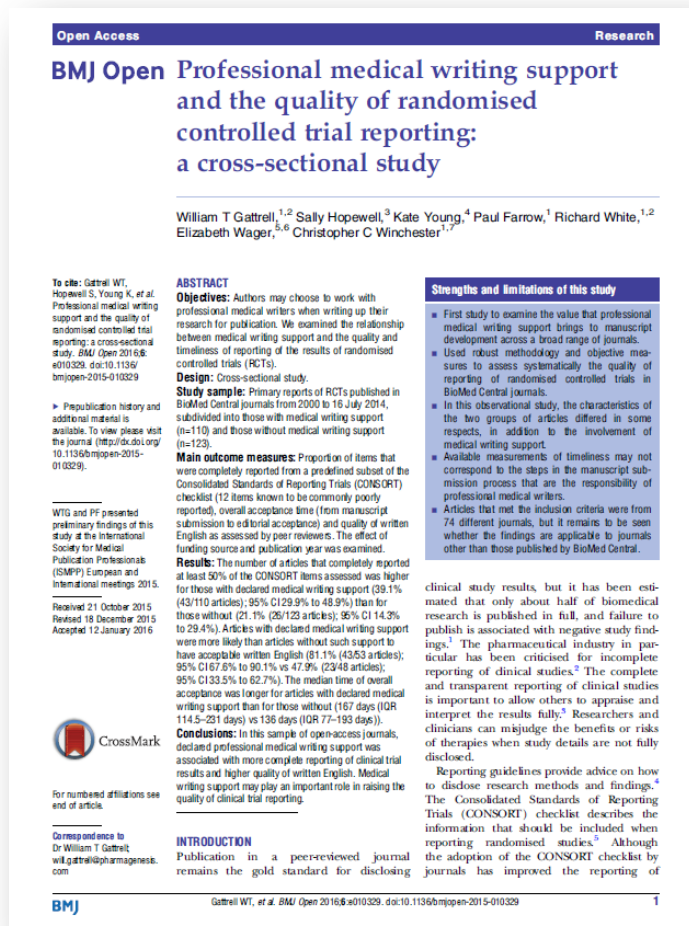
Woolley KL et al. Poor compliance with reporting research results – we know it’s a problem ... how do we fix it? Curr Med Res Opin 2012;28:1857–60

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

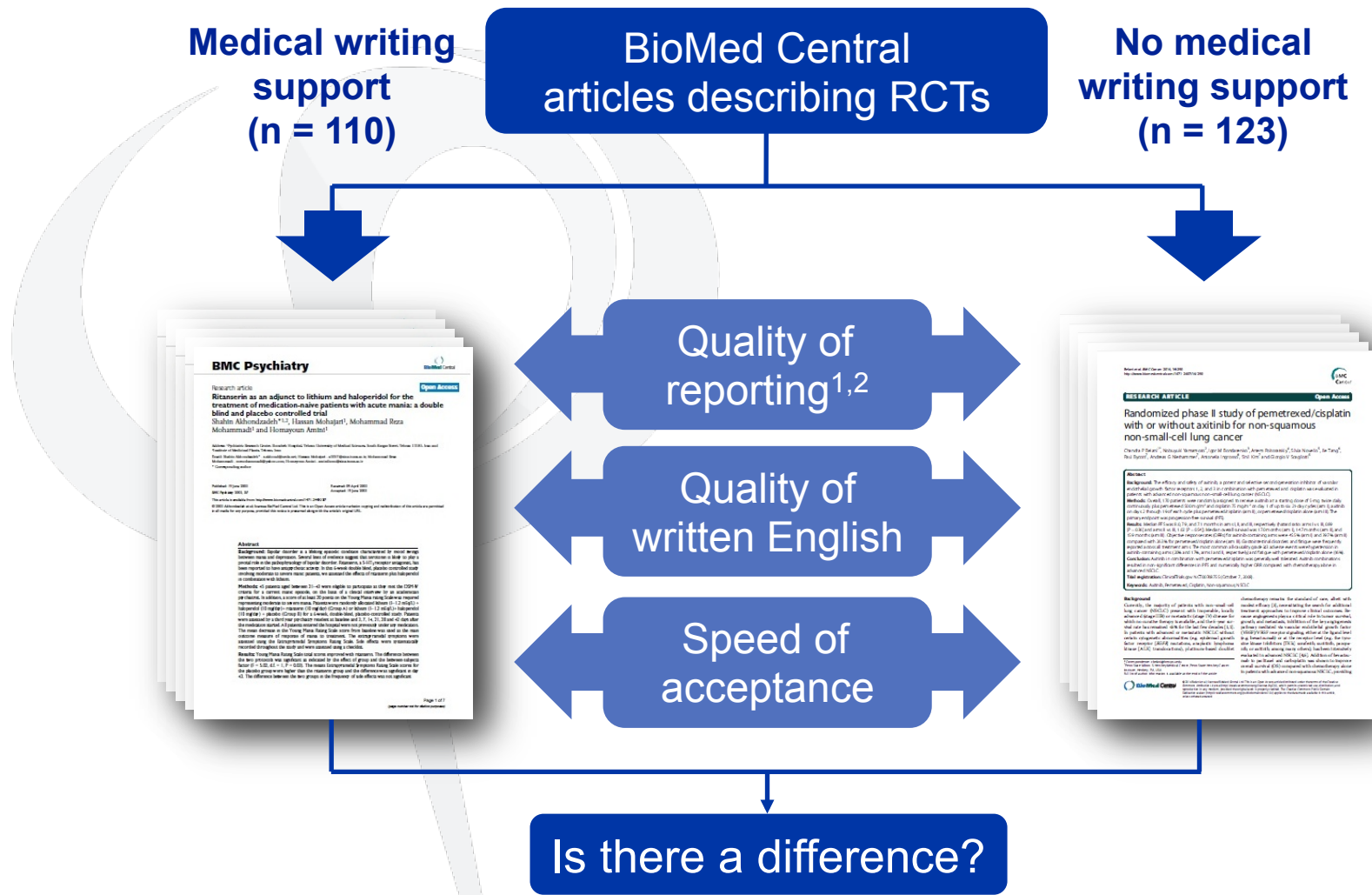
24. Bailey M. Science editing and its effect on manuscript acceptance time. *AMWA Journal* 2011;26:147–52

Peer-reviewed evidence of the value of medical writing support



- Collaboration with experts in publications ethics and reporting standards
 - Liz Wager (author of GPP1 and GPP3, COPE)
 - Sally Hopewell (Oxford Clinical Trials Unit, CONSORT)
- Awarded best research prize at Annual and European meetings of ISMPP in 2015
- Published in *BMJ Open* in February 2016
 - Impact factor: 2.3

Study design



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 ...

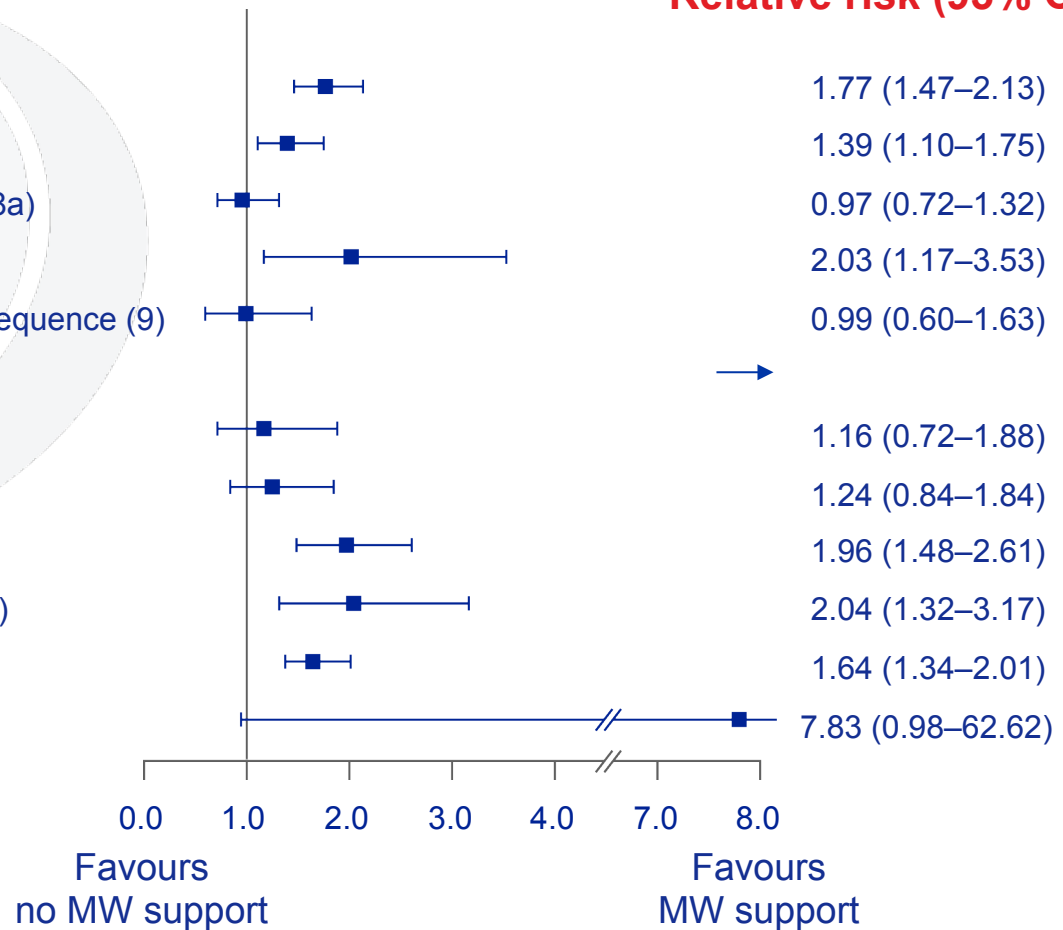


CONSORT item (number)

- 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)

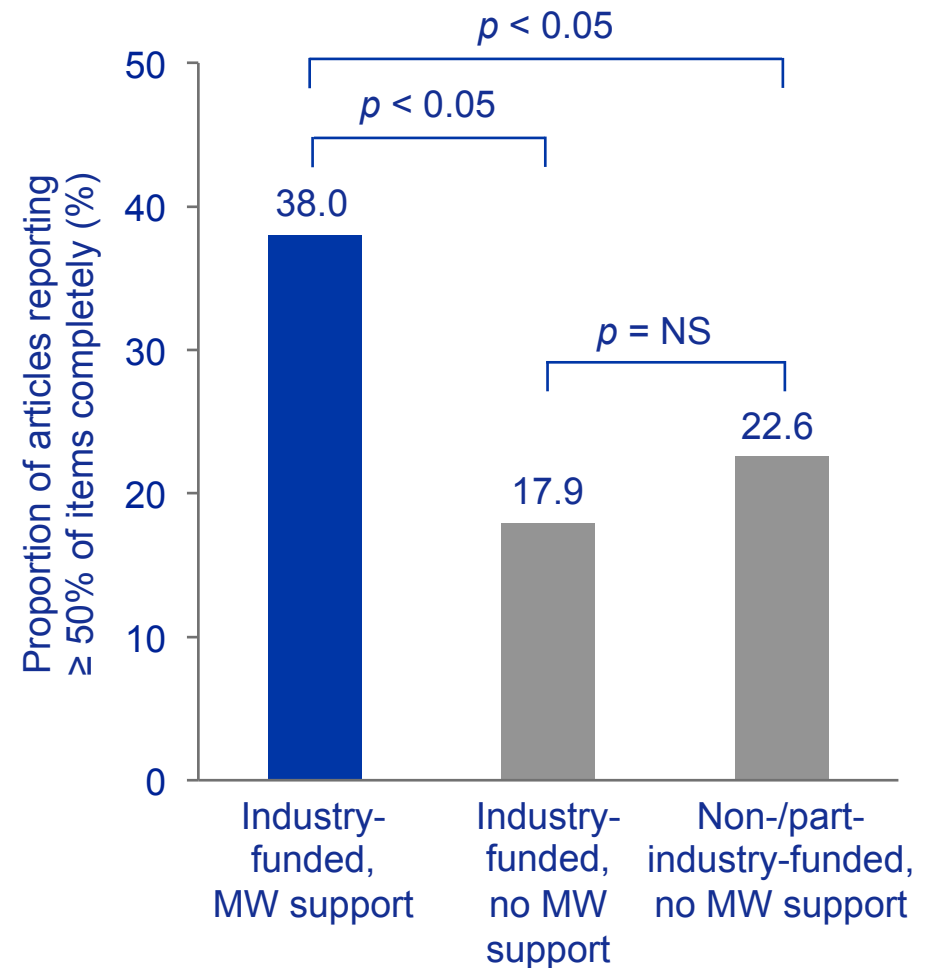
Items were chosen that are often poorly reported

Relative risk (95% CI)



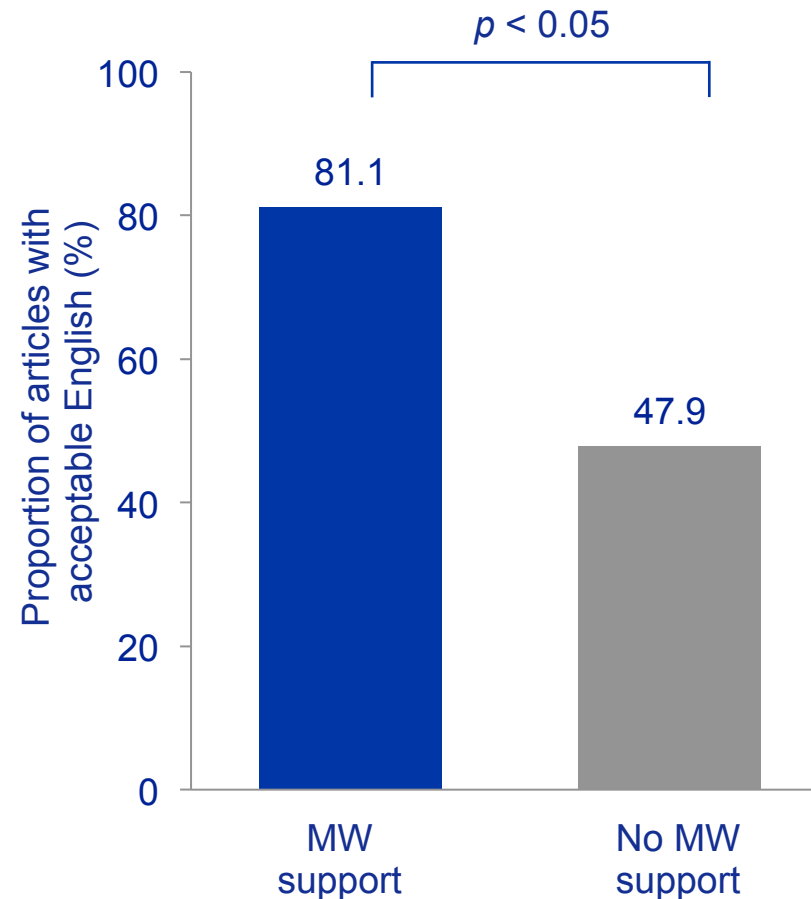
... irrespective of funding source

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



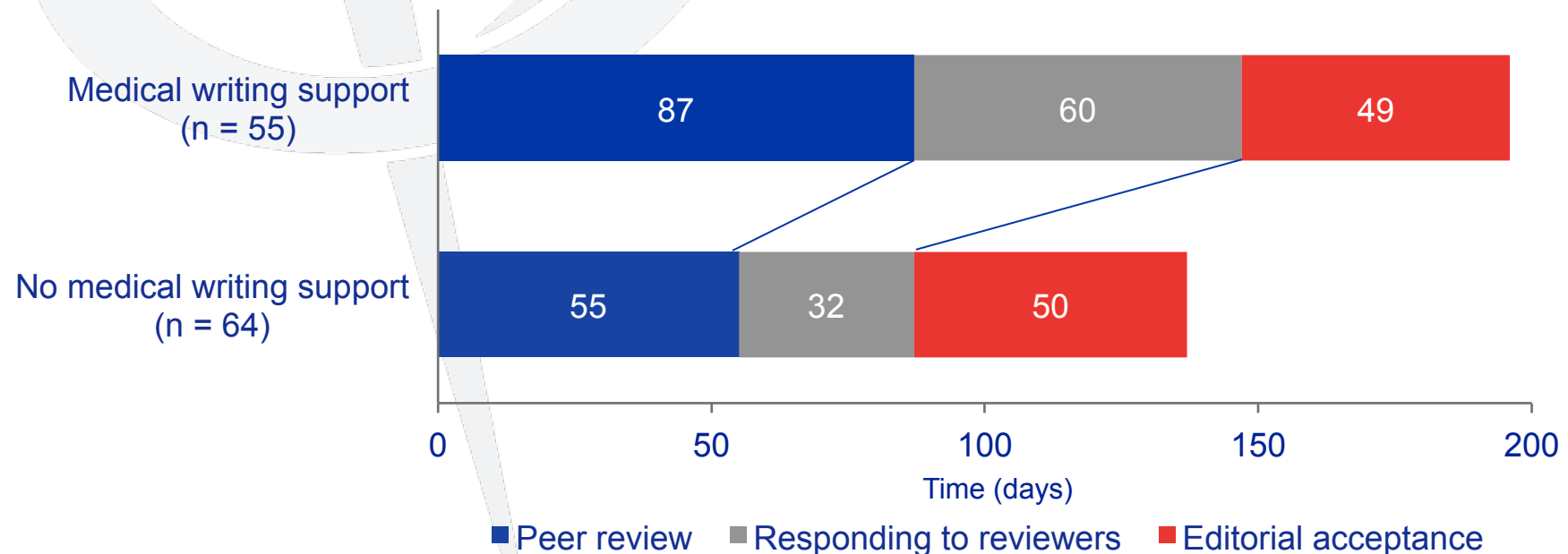
Improved quality of written English

- 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



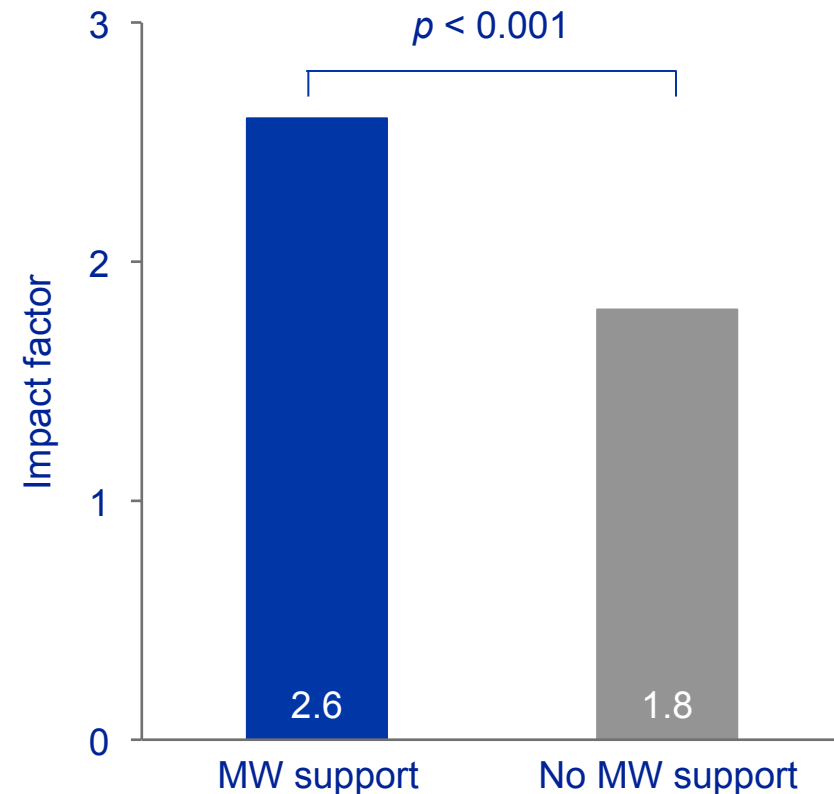
Slight reduction in speed of acceptance

- Median time from submission to acceptance was longer for articles with medical writing support than for those without
 - 23.9 versus 19.4 weeks ($p < 0.01$)
 - Attributable to increased time for peer review and responding to reviewers



Accepted in higher impact journals ...

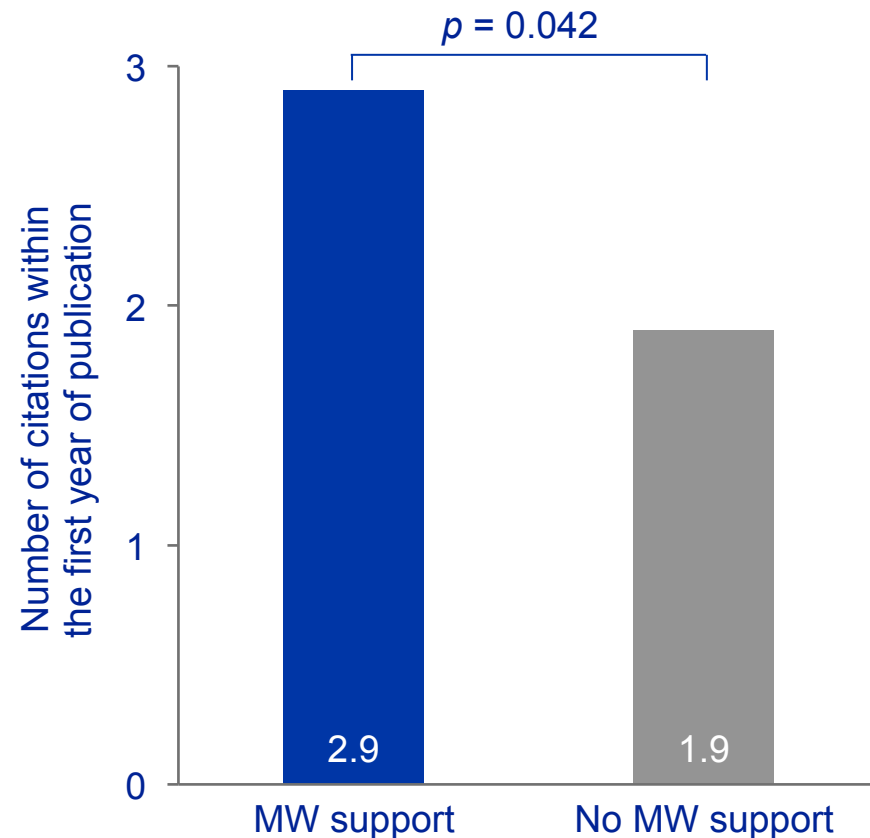
- Also true for the subgroup of industry-sponsored articles with (n = 108) and without medical writing support (n = 39)
- Mean impact factor: 2.6 vs 1.8; $p < 0.001$



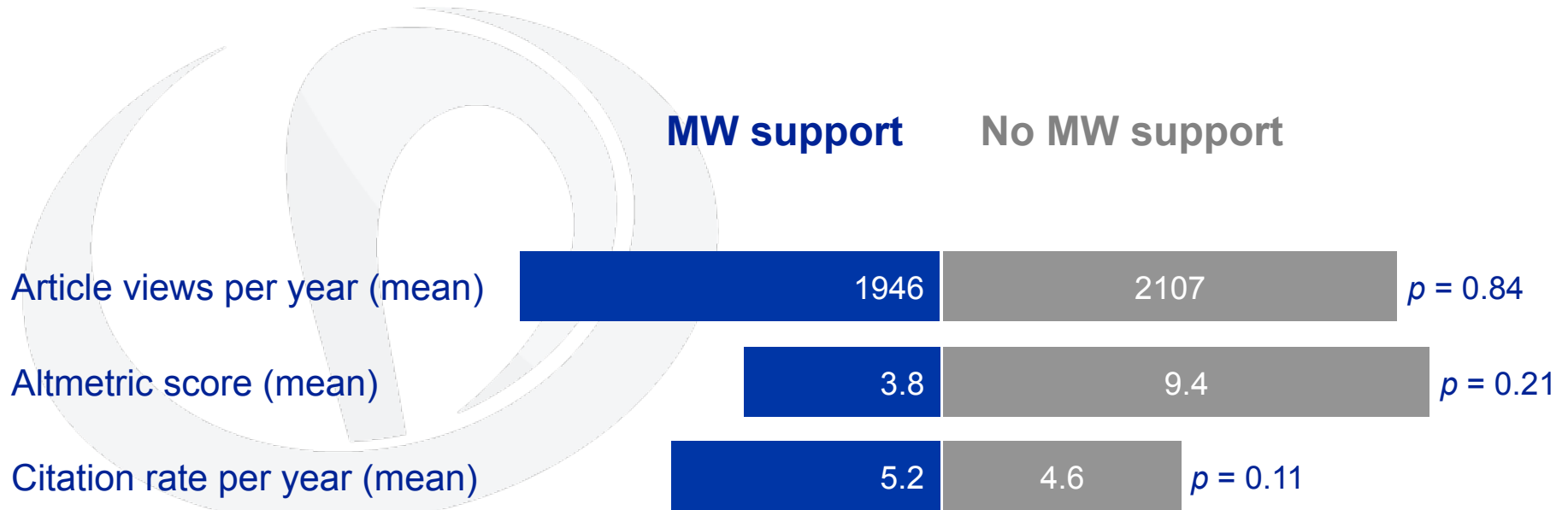
... and receive an increased number of citations in the first year



- For the subgroup of industry-sponsored articles with and without medical writing support, mean number of citations within the first year: 2.9 vs 1.9; $p = 0.542$



No significant differences in other measures of article impact



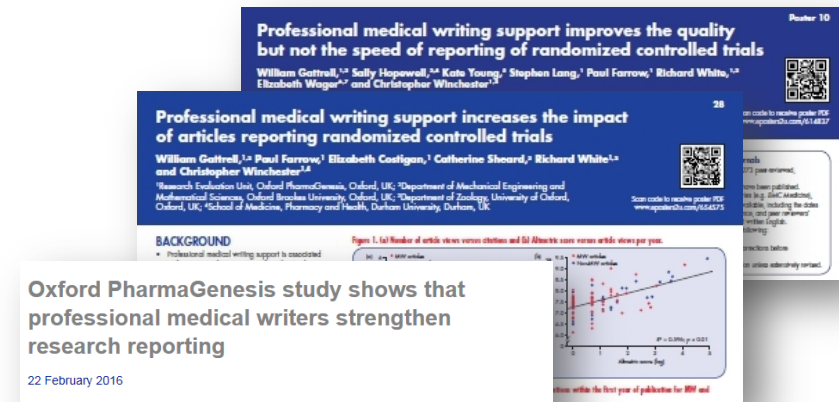
Study conclusions

- Declared medical writing support is associated with higher quality reporting of RCTs, compared with no writing support
 - Other differences between the study groups do not explain findings
- Secondary analyses suggest that articles with medical writing support are accepted in higher impact journals
 - Articles with medical writing support were published more recently
- First study to demonstrate convincingly the value of medical writing support
- Further research is warranted



How did we make our voice heard?

- ISMPP posters
- News article
- Twitter direct messages to influential tweeters
- Twitter take-over
- Press release
- Author videos
- With support from
 - Peter Llewellyn (MedComms Networking)
 - Ryan Woodrow (The Publication Plan)



Oxford PharmaGenesis study shows that professional medical writers strengthen research reporting

22 February 2016



Professional medical writing support improves the quality of

EMBARGOED
Not for publication before 00:01 hours on 22 February 2016

Press release

New study reveals that professional medical writers strengthen research reporting
Award-winning research published in BMJ Open
the University of Oxford and the University of Sheff Hallam, demonstrates for the first time how medical writing support




Richard White talks about the Oxford PharmaGenesis BMJ Open article



Will Gattrell talks about our new study published today in BMJ Open

The warm reaction

Trish Groves @trished · Feb 29
 @OxPharmaGenesis @BMJ_Open Nice video about your paper, too
youtu.be/4MlrZ6HCm2M

Richard Smith @Richard56
 81% of studies with medical writers have "acceptable English" compared with 48% without
<https://t.co/8NUrg4ZxzC>

Adam Jacobs @statsguyuk · Feb 23
 Well deserved: it's an important paper. #medcomms #alltrials #medicalwriting

Oxford PharmaGenesis @OxPharmaGenesis
 Very excited that our article in @BMJ_Open has had 902 downloads in 2 days! Take a look: tinyurl.com/jjexy6q #pubplan #medcomms #ismpp

peter llewellyn @networkpharma · Feb 23
 IMO #medcomms needs more of this type of activity!

Oxford PharmaGenesis @OxPharmaGenesis
 Thanks to all of you, our research has reached 40 000 followers and is in the top 5% of research scored by @Altmetric #pubplan #medcomms

Official_EMWA @Official_EMWA · Feb 22
 Award-winning study @BMJ_Open reveals that professional #medicalwriting strengthens research reporting
ow.ly/YAWVh

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ABOUT

New study reveals that professional medical writers strengthen research reporting
 Posted on February 22, 2016 by Aspire Scientific Ltd

News of interest to Medical Writers: *BMJ Open* paper on medical writing

EMWA would like to draw your attention to the recently published *BMJ Open* paper titled, "Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study."

Professional medical writing support improves the quality of clinical trial reporting, according to award-winning research shows that compliance with reporting guidelines in medical journals doubles when medical writers are involved. The quality of written English is also significantly improved when medical writing support is used.

Read the paper in full [by clicking here](#).

If you spot any future stories of interest and relevance to EMWA members, please forward them to webmanager@emwa.org.

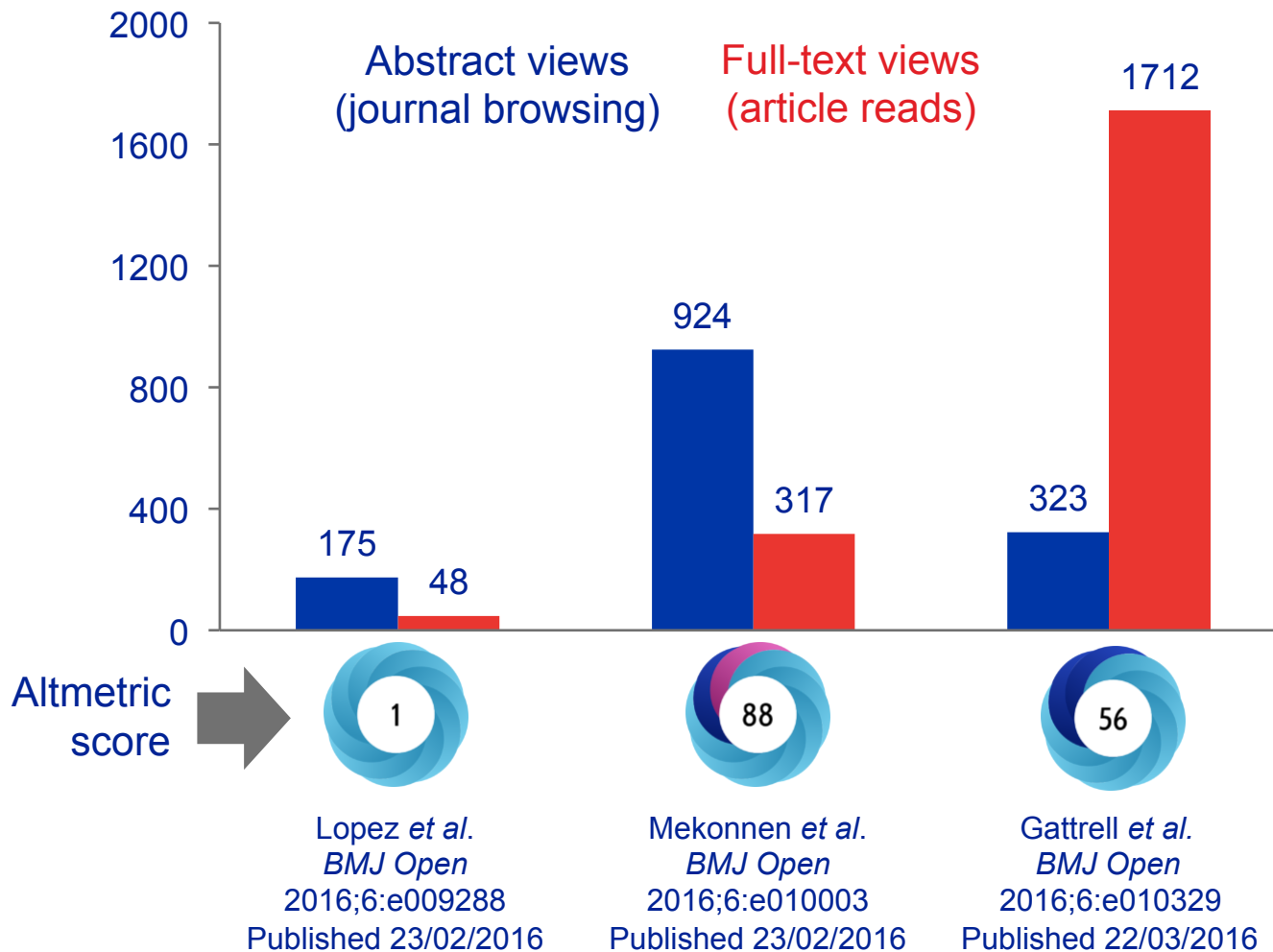
76

- Blogged by 1
- Tweeted by 88
- On 4 Facebook pages

[Click for more details](#)

So far, Altmetric has seen 154 tweets from 88 users, with an upper bound of 86,957

Reach after 5 days



Podcasts | Most read | Blog

- Research: [Bicycling injury hospitalisation rates in Canadian jurisdictions: analyses examining associations with helmet legislation and mode share](#) (2 Nov 2015)
- Research: [Registered nurse, healthcare support worker, medical staffing levels and mortality in English hospital trusts: a cross-sectional study](#) (9 Feb 2016)
- Research: [Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study](#) (21 Feb 2016)
- Research: [Social group memberships in retirement are associated with reduced risk of premature death: evidence from a longitudinal cohort study](#) (16 Feb 2016)

3497 full-text views so far

How can our evidence be used?

- 87% positive impact, ~75% had or would use this evidence



ACCOUNTABILITY IN RESEARCH
2016, VOL. 23, NO. 3, 178-194
http://dx.doi.org/10.1080/08989621.2015.1088788

Taylor & Francis
Taylor & Francis Group

Mythbusting Medical Writing: Goodbye, Ghosts! Hello, Help!
Cindy W. Hamilton, Ph.D., Jackie Marchington, Ph.D., and Karen Woolley, Ph.D.

EDITORIALS

Are prolific authors too much of a good thing?
Dominant authors can lead to an imbalance of power within an evidence base
Elizabeth Wager, publications consultant
Plymouth, UK

International Society for Medical Publication Professionals (ISMPP)

Dear Colleagues,

As many of you are aware, late last year the China Association for Science and Technology (CAST) and seven leading scientific organizations and ministries, including the Chinese Academy of Sciences, the Chinese Academy of Engineering, the Ministry of Science and Technology and the Ministry of Education, jointly announced a

Authors

Clients

Critics

Leaders

What's this?

Responses to this article

Response to Gattrell et al., Professional Medical Writing Support and the Quality of Randomised Controlled Trial Reporting: A Cross-Sectional Study
Thomas A Lang
BMJ Open published online April 1, 2016
[Full text]

16
EvidenceLive
University of Oxford June 22 - 24 2016

gappteam.org

Hamilton CW *et al.* *Account Res* 2016;23:178-94; Wager E. *BMJ* 2015;351:h2782
ISMPP: An Important Announcement about the CAST directive (31 March 2016).

Acknowledgements

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Gattrell WT *et al.* Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study. *BMJ Open* 2016 21;6:e010329
<http://bmjopen.bmj.com/content/6/2/e010329.full>

Gattrell W *et al.* Professional medical writing support increases the impact of articles reporting randomized controlled trials. *Curr Med Res Opin* 2016; 32(Suppl 1):S17. 12th International Meeting of ISMPP, 11–13 April 2016
<http://www.eposters2u.com/654575/>