

AVENELL, A., ROBERTSON, C., BOACHIE, C., STEWART, F., ARCHIBALD, D., DOUGLAS, F., HODDINOTT, P. and VAN TEIJLINGEN, E. 2016. Re: Sex-based subgroup differences in randomized controlled trials: empirical evidence from Cochrane meta-analyses. *BMJ* [online] 355. Available from: <https://www.bmj.com/content/355/bmj.i5826/rr>.

Re: Sex-based subgroup differences in randomized controlled trials: empirical evidence from Cochrane meta-analyses.

AVENELL, A., ROBERTSON, C., BOACHIE, C., STEWART, F., ARCHIBALD, D., DOUGLAS, F., HODDINOTT, P. and VAN TEIJLINGEN, E.

2016



Rapid Response:

Re: Sex based subgroup differences in randomized controlled trials: empirical evidence from Cochrane meta-analyses

Alison Avenell

Clinical Chair in Health Services Research Clare Robertson, Charles Boachie, Fiona Stewart, Daryll Archibald, Flora Douglas, Pat Hoddinott, Edwin van Teijlingen

Health Services Research Unit, University of Aberdeen

Health Sciences Building, Foresterhill, Aberdeen, Scotland, AB25 2ZD

We enjoyed reading the recent analysis of sex-based subgroup differences in randomized controlled trials in the Cochrane Library from Wallach and colleagues (1). The authors found little evidence for clinically relevant sex-treatment interactions for outcomes.

There are social, psychological and contextual factors that may influence men's and women's participation, engagement and adherence to health interventions, services and trial procedures, particularly for programmes that aim to change health-related behaviours, which would not be apparent in this analysis. For example, men are much less likely than women to take part in trials and services providing weight loss programmes for obesity management (2,3). In an attempt to examine the reasons for this, and help develop interventions which are more likely to engage men in participation and continuation with weight loss programmes, we undertook a mixed-methods systematic review of qualitative and quantitative evidence (including randomized controlled trials) of weight management for men who were obese (2). This led to new guidance endorsed by Public Health England on weight management for men (4).

In our review we undertook a pre-specified analysis of dropouts by sex from trials in our systematic review, where individual trials presented data separately for men and women. This showed that, although men were less likely to participate in weight loss trials, they were more likely to be trial completers than women with an absolute difference of 11% (95% CI 8% to 14%) (5). We would like to highlight that sex, and gender, can affect the way we behave, our motivation, our perceptions of the world around us and ourselves, and our reasons for changing (or not) our behaviours.

References

1. Wallach JD, Sullivan PG, Trepanowski JF, Steyerberg EW, Ioannidis JP. Sex based subgroup differences in randomized controlled trials: empirical evidence from Cochrane meta-analyses. *BMJ* 2016;355:i5826
2. Robertson C, Archibald D, Avenell A, Douglas F, Hoddinott P, van Teijlingen E, Boyers D, Stewart F, Boachie C, Fioratou E, Wilkins D, Street T, Carroll P, Fowler C. Systematic reviews of and integrated report on the quantitative, qualitative and economic evidence base for the management of obesity in men. *Health Technol Assess* 2014;13:35
3. Pagoto SL, Schneider KL, Oleski JL, Luciani JM, Bodenlos JS, Whited MC. Male inclusion in randomized controlled trials of lifestyle weight loss interventions. *Obesity* 2012;20:1234-9.
4. Men's Health Forum and Public Health England. How to make weight loss services work for men. https://www.menshealthforum.org.uk/sites/default/files/pdf/how_to_weight...
5. Robertson C, Avenell A, Boachie C, Stewart F, Archibald D, Douglas F, Hoddinott P, van Teijlingen E, Boyers D, Boachie C. Should weight loss and maintenance programmes be designed differently for men? A systematic review of long-term randomised controlled trials presenting data for men and women: The ROMEO Project. *Obesity Res Clin Pract* 2016;10:70-84.

Competing interests: No competing interests