



LETTERS

SEX BASED DIFFERENCES IN TRIALS

Sex can affect participation, engagement, and adherence in trials

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We enjoyed Wallach and colleagues' analysis of sex based subgroup differences in randomised controlled trials in the Cochrane Library.¹ The authors found little evidence for clinically relevant sex-treatment interactions for outcomes.

Not apparent in their analysis are the social, psychological, and contextual factors that can influence men's and women's participation, engagement, and adherence to health interventions, services, and trial procedures, particularly for programmes to change health related behaviours. For example, men are much less likely than women to take part in trials of weight loss programmes for obesity management.^{2,3}

To examine the reasons for this, and to help develop interventions that are more likely to engage men to participate in and continue with weight loss programmes, we undertook a mixed methods systematic review of qualitative and quantitative evidence (including randomised 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

We performed a pre-specified analysis of dropouts from trials by sex, 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 complete the trial than women, with an absolute difference of 11% (95% confidence interval 8% to 14%).⁵ Sex, and gender, can affect the way we behave, our motivations, our perceptions of the world around us and ourselves, and our reasons for changing (or not) our behaviours.

Competing interests: None declared.

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- 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 (Silver Spring)* 2012;20:1234-9. doi:10.1038/oby.2011.140 pmid:21633403.
- 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_final_lr_1.pdf
- 5 Robertson C, Avenell A, Boachie C, et al. 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. *Obes Res Clin Pract* 2016;10:70-84. doi:10.1016/j.orcp.2015.04.005 pmid:25937165.

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