BJS, 2023, **110**, 1896
https://doi.org/10.1093/bjs/znad304
Advance Access Publication Date: 20 September 2023
Correspondence

Comment on: Two decades of surgical randomized controlled trials: worldwide trends in volume and methodological quality

Xiya Ma[1,*] and Dominique Vervoort[2,3]

[1]Division of Plastic Surgery, Department of Surgery, Université de Montréal, Montréal, Québec, Canada
[2]Division of Cardiac Surgery, University of Toronto, Toronto, Ontario, Canada
[3]Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, Canada

*Correspondence to: Xiya Ma, Division of Plastic Surgery, Department of Surgery, Université de Montréal, 2900 Edouard Montpetit Blvd, Montréal, Québec, H3T 1J4, Canada (e-mail: xiyama.xm@gmail.com)

Dear Editor

RCTs represent the gold standard for evidence generation. Pronk *et al.*[1] reviewed surgical RCTs over a span of 20 years, finding an improvement in trial quality along with a rise in Asia, mostly led by China. Pronk *et al.*[1] focused on progress in reported methodology and study design, but did not consider improvements in terms of equity and, consequently, the generalizability of current trials, which ought to be considered a form of quality.

Inequity may present at the trialist level and among patients enrolled in RCTs, both commonly disproportionately dominated by white men in high-income countries. Pronk *et al.*[1] showed that, despite some geographical shift, only one lower-middle-income country (Egypt) was featured in the top 10 in terms of trial volume in 2019, whereas Africa and South America together represented the smallest number of trials at 6.8 per cent of the total volume, despite being home to nearly one-quarter of the world's population. This challenges the generalizability of trials, as interventions that work within a given country or region do not account for cultural, political, and economical factors that may influence behaviours and outcomes elsewhere. Further, under-enrolment of women and minoritized and racialized populations has been found among trials in high-income countries. Thus, even results within the same country may be difficult to generalize to its entire population.

Barriers to improving equity in RCTs are manifold, including high costs, complex logistics, long timelines, and difficulties with data infrastructure and follow-up, which render these opportunities less accessible to researchers in variable-resource contexts, where context-appropriate evidence is especially highly needed. Moreover, imbalances in trialist networks perpetuate biases that result in under-enrolment of under-represented populations. Future directions should include increased mentorship and collaboration to empower early-career trialists, more representative trial teams, and more pragmatic and lower-cost solutions to RCTs.

Author contributions

Xiya Ma (Conceptualization, Writing—original draft, Writing—review & editing), and Dominique Vervoort (Conceptualization, Methodology, Supervision, Writing—original draft, Writing—review & editing).

Reference

1. Pronk AJM, Roelofs A, Flum DR, Bonjer HJ, Abu Hilal M, Dijkgraaf MGW *et al.* Two decades of surgical randomized controlled trials: worldwide trends in volume and methodological quality. *Br J Surg* 2023;**110**:1300–1308

Received: July 10, 2023. **Accepted:** July 10, 2023
© The Author(s) 2023. Published by Oxford University Press on behalf of BJS Society Ltd.
This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (https://creativecommons.org/licenses/by-nc/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com