Reviewer’s report

Title: Design, planning and implementation lessons learnt from a surgical multi-centre Randomised Controlled Trial

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Reviewer: Thomas Pinkney

Reviewer's report:

This article has an interesting premise but I think it needs to be improved prior to being reassessed prior to any possible publication

Overall:

The abstract (and paper) is internally inconsistent in that it states that forecasting work ensured that the recruitment window was of adequate length, then a couple of lines later that real-time monitoring meant you could extend the recruitment window in a timely fashion!

Having referenced statements within the results section is unusual; I would suggest these should either be in the background or, more likely, in the discussion.

There is some over-generalisations made from the reported literature - for example in the question of optimal timing of endpoint assessment (relative to day of randomisation or day of intervention) - and a statement is made that this "makes little difference to the reported outcomes" - but this is based on evidence from one random orthopaedic trial. As such, this is probably a misleading and potentially even an irresponsible statement to make.

Numerous links to figures etc were missing, with an error message given instead - which made the paper hard to navigate/understand.
One of the key concepts in the paper is the authors using 'reference class' forecasting of consent rates. But in the relevant section of the methods, this concept is not introduced or described at all - and as such the uninitiated reader will not be able to gain much from this.

I doubt that the sections on attribution and reimbursement of costs, and how this was done within the UK system will be of any interest to international readers. It doesn't add much to the paper either.

The prize draw for improving questionnaire return - this concept is incompletely introduced in the methods, then effectively ignored for the rest of the paper. It should be expanded, with more discussion of evidence behind this (of which there is plenty) and discussion of potential ethical issues involved.

Other specific points:

The background sets the scene fairly well but has some confusing parts - such as in line 52 - what does n=36 mean? Is it 36 out of 81 out of 395 within the particular reference being discussed? Then the next sentence appears to be discussing the same source, yet is then referenced as source '5-7' which makes no sense.

Line 59 - in the introduction of type 3 surgical trials; comparing medicine with surgery; you state that surgeon equipoise can be an issue - but what about non-surgeons? They definitely can have a lack of equipoise in this situation. Suggest change to 'clinician'

Line 128 - "For type 3 surgical trials, conversion rates NEVER exceed one patient consented for every five screened…". This is a very strong statement, and whilst the 11 year old review article and the single small trial in GORD may support it mathematically, nothing is ever this black and white. It should be toned down.

Line 148-149-150 - this sentence makes no sense and needs to be rewritten
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