

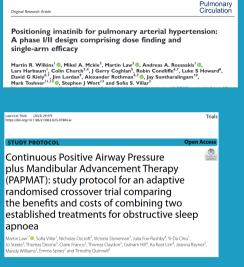


Publishing a Protocol: lived experience

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Why publish the trial protocol?

- Increased validity;
- Helps other researchers:
 - Plan study with similar design;
 - Know that this study is taking place and its details (beyond clinicaltrials.gov);
- Increased impact;
- Publish or perish! Rare opportunity for applied statisticians to be the first author;
- May be the only published paper from the study.

How to publish the trial protocol

- Choose a journal (spoiler alert: it's Trials);
- Use the journal's template and share it.

Authorship

See https://www.icmje.org.

Same criteria as any other published manuscript:

- Substantial contributions to the conception/design of the work; or the acquisition/analysis/interpretation of data for the work; AND
- Drafting/critically reviewing the intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work.

Aside: The Statistical Analysis Plan

Publish this too! How? For *Trials* at least, in one of the following ways:

- Directly within the submitted protocol (if trial is simple);
- As an appendix alongside the submitted protocol;
- As an "addendum"/update to a published protocol;
- As a completely separate submission (inc. authors and DOI)

Practical lessons

- Your CTU's template may be very different to the journal's template, so consider updating your CTU's own templates to match the journal's.
- Start early:
 - If "converting" a protocol to the journal template, this becomes harder the more developed the protocol is.
 - If using the journal template as a guide only, there is still a great deal of work to be done.
- Expect it to take a long time, so...
- Get buy-in from co-authors!

Discussion

What is your experience of publishing trial protocols?