Author’s response to reviews

Title: Protocol for a Systematic Review of N-of-1 trial protocol guidelines and protocol reporting guidelines

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Author’s response to reviews:

Dear Sue Harnan,

Thank you very much for your additional suggestions. Please see our responses for each, below. We would be happy to address any further questions or suggestions that may arise.

Sincerely,

Sunita Vohra.

REVIEWER: Sentence "Due to lack of specificity, articles that simply describe a generic ABAB trial design for the purpose of reviewing or contrasting different trial designs, or that pertain to other single subject research designs, will also be excluded." needs editing to remove "also", as there are now no longer any other exclusion criteria.

RESPONSE: Agreed. “also” has been removed. (Line 127)

REVIEWER: Sentence "Practice and verification of the data extraction form and process using the N-of-1 guidance documents will occur before undertaking the data extraction." - This
sentence doesn't sound quite right. We more usually use the term "piloting" of a data extraction form.

RESPONSE: Agreed. Piloting encompasses both practice and verification, and both the form itself and our process. Therefore we have changed it to: “Piloting of the data extraction form using the N-of-1 guidance documents will occur...” (Line 173)

REVIEWER: sentence "...One reviewer will extract (AP), and a second (SP) will check a 15% sample from each paper for extraction accuracy." It is more usual to check a 15% sample of papers (rather than items in the DE form), but perhaps you have a good reason for doing it this way? I don't think it really matters, but thought I'd mention it.

RESPONSE: Thank you. We will consider that for future SRs. For this SR, the basis for developing a SPIRIT N-of-1 protocols reporting guideline (SPENT), the guideline team want to keep it parallel to the SR process used for the sister CENT reporting guideline (CONSORT N-of-1 guideline).

REVIEWER: "qualitative-identified" - should maybe be "qualitatively-identified"?

RESPONSE: Agreed, and changed. (Line 195)