Appendix 1 The detail development of method of this guidance

Acupuncture Definition

The World Health Organization has defined acupuncture as any type of intervention involving the penetration of the skin with needles or stimulation of specific points with other methods regardless of its theoretical basis [1].

A) Structure and development of acupuncture trials guidance

Our research group conducted a systematic survey [2] to identify the most prevalent trial design and execution issues and factors associated with the magnitude of acupuncture treatment effects. This search included Medline, Embase, Cochrane Central Register of Controlled Trials, China National Knowledge Infrastructure, Wanfang Database, VIP Database, and China Biology Medicine disc from 2015 to April 2019, to include trials with more than 100 randomized patients, at least one patient-important outcome, and reported at least one of two sets of comparisons: acupuncture versus no intervention, sham acupuncture or waiting list; or acupuncture plus conventional medical treatment versus conventional medical treatment with or without sham acupuncture.

The systematic survey used a standard data collection form to extract key information related to trial design and execution, including 46 methodological and clinical factors as independent variables that might be associated with the magnitude of effect. The meta-regression used standardized mean difference (SMD) as effect estimate and dependent variable.

The expert panel provided feedback on the data extraction forms. The steering committee reviewed and discussed the systematic survey's data analysis and the methodological challenges raised in an analysis article part of the BMJ acupuncture collection [3]. The steering committee prioritized unique and most prevalent issues in acupuncture trials and drafted an initial version of this guidance, including key questions, advice, and real acupuncture trial examples informed by the systematic survey's data.

B) Piloting and user feedback

We conducted the pilot testing and users' feedback using an iterative approach. The steering committee drafted the initial document that the expert panel reviewed and provided feedback. Through video conferences and email exchanges, we had a discussion with both groups of panelists and, on occasion, individuals. –The steering

committee incorporated feedback and modified the guidance documents accordingly. The steering committee considered the process complete when the expert panel reached the consensus that the guidance content and presentation could not, at this juncture, be further improved.

References

1 Acupuncture: Review and analysis of reports on controlled clinical trials. Geneva: World Health Organization. World Health Organization 2003.

2 Gang WJ, Xiu WC, Shi LJ, *et al*, Factors Associated with the Magnitude Of acUpuncture treatment effectS (FAMOUS): a meta-epidemiological study of acupuncture randomized controlled trials. ARTICLE PART OF COLLECTION - NOT PUBLISHED YET.

3 Fei YT, Cao HJ, Xia RY, *et al*, Methodological challenges in design and conduct of randomised controlled trials in acupuncture. BMJ. 2022 Feb 25;376:e064345. doi: 10.1136/bmj-2021-064345.~~Methodological challenges in the design and conduct of randomized controlled trials in acupuncture. ARTICLE PART OF COLLECTION - NOT PUBLISHED~~