Appendix Table. **Proposed Elaborations of CONSORT Items for Randomized, Controlled Trials of Herbal Medicine Interventions***

Paper Section and Topic	Item Number	Descriptor	Reported on Page Number
Title and Abstract	1	How participants were allocated to interventions (e.g., "random allocation," "randomized" or "randomly assigned"). *Either the title or abstract, or both, should state the herbal medicinal product's Latin binomial, the part of the plant used, and the type of preparation.*	1
Introduction			
Background	2	Scientific background and explanation of rationale. *Including a brief statement of reasons for the trial with reference to the specific herbal medicinal product being tested and, if applicable, whether new or traditional indications are being investigated.*	3
Methods			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected. *If a traditional indication is being tested, a description of how the traditional theories and concepts were maintained. For example, participant inclusion criteria should reflect the theories and concepts underlying the traditional indication.*	4
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	4
	4A: Herbal medicinal product name	*1. The Latin binomial name and the botanical authority and family name for each herbal ingredient; common name(s) should also be included.* *2. The proprietary product name (i.e., brand name) or the extract name (e.g., EGb-761) and the name of the manufacturer of the product.* *3. Whether the product used is authorized (licensed, registered) in the country in which the study was conducted.*	4
	4B: Characteristics of the herbal product	*1. The part(s) of plant used to produce the product or extract.* *2. The type of product used (e.g., raw [fresh or dry], extract).* *3. The type and concentration of extraction solvent used (e.g., 80% ethanol, 100% H_2O, 90% glycerine, etc.) and the ratio of herbal drug to extract (e.g., 2 to 1).* *4. The method of authentication of raw material (i.e., how done and by whom) and the lot number of the raw material. State if a voucher specimen (i.e., retention sample) was retained and, if so, where it is kept or deposited, and the reference number.*	4
	4C: Dosage regimen and quantitative description	*1. The dosage of the product, the duration of administration, and how these were determined.* *2. The content (e.g., as weight, concentration; may be given as range where appropriate) of all quantified herbal product constituents, both native and added, per dosage unit form. Added materials, such as binders, fillers, and other excipients (e.g., 17% maltodextrin, 3% silicon dioxide per capsule), should also be listed).* *3. For standardized products, the quantity of active/marker constituents per dosage unit form.*	4
	4D: Qualitative testing	*1. Product's chemical fingerprint and methods used (equipment and chemical reference standards) and who performed the chemical analysis (e.g., the name of the laboratory used). Whether a sample of the product (i.e., retention sample) was retained and if so, where it is kept or deposited.* *2. Description of any special testing/purity testing (e.g., heavy metal or other contaminant testing) undertaken; which unwanted components were removed and how (i.e., methods).* *3. Standardization: what to standardize (e.g., which chemical components of the product) and how (e.g., chemical processes, or biological/functional measures of activity).*	4
	4E: Placebo/control group	*The rationale for the type of control or placebo used.*	4
	4F: Practitioner	*A description of the practitioners (e.g., training and practice experience) who are a part of the intervention.*	N/A
Objectives	5	Specific objectives and hypotheses.	3
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors). *Outcome measures should reflect the intervention and indications tested considering, where applicable, underlying theories and concepts.*	5
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	5
Randomization			
Sequence allocation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).	4
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	4
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	4

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Appendix Table—**Continued**

Paper Section and Topic	Item Number	Descriptor	Reported on Page Number
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	5
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	5
Results			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	flow chart attached
Recruitment	14	Dates defining the periods of recruitment and follow-up.	5
Baseline data	15	Baseline demographic and clinical characteristics of each group. *Including concomitant medications, herbal and complementary medicine use.*	5
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	5
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	5-6
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	N/A
Adverse events	19	All important adverse events or side effects in each intervention group.	7
Discussion			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes. *Interpretation of the results in light of the product and dosage regimen used.*	7-8
Generalizability	21	Generalizability (external validity) of the trial findings. *Where possible, discuss how the herbal product and dosage regimen used relate to what is used in self-care and/or practice.*	9
Overall evidence	22	General interpretation of the results in the context of current evidence. *Discussion of the trial results in relation to trials of other available products.*	8

* CONSORT items (1, 17) are listed in normal text. Proposed recommendations for reports of herbal medicine and randomized, controlled trials are listed in italicized text.
CONSORT = Consolidated Standards of Reporting Trials.