Behavioral/Nonpharmacological Clinical Trials Checklist for *Headache*

Checklist of items to include in reports of clinical trials evaluating behavioral/nonpharmacological therapies. An unofficial extension of the CONSORT Statement (and extension to randomized trials of nonpharmacologic treatments) adapted from *Guidelines for Trials of Behavioral Treatments for Recurrent Headache*[1]

Section and Topic	*Item No.*	*Descriptor*	*Page No.*
Abstract	1	(a) principal research question(s) and design [C1][2]	
		(b) balanced summary of methods and principal findings	
Introduction	2	(a) scientific background and rationale for study [C2]	
		(b) research objectives and hypotheses [C5]	
Methods Selection of Patients	3	(a) patient eligibility criteria and settings and locations where data were collected [C3]	
		(b) sources of patients	
		(c) recruitment methods	
		(d) inducements for participation	
		(e) whether or not patients sought treatment	
		(f) diagnosis using ICHD-II diagnostic criteria[3] and chronicity	
		(g) baseline symptom frequency and severity criteria	
		(h) criteria for pertinent medical and psychiatric comorbidities	
Trial Design and Execution	4	(a) research design (e.g., case report, single case experimental design, single-group outcome study, parallel group outcome study) and control conditions (if implemented)	
		(b) method for sample size determination, and when applicable, (a) explanation of stopping rules of interim analyses, and (b) details of any clustering by centers or care providers [C7]	
		(c) method for allocating patients to conditions (e.g., randomization, stratification) [C8, C9, C10, C11]	
		(d) whether patient, therapist, and outcome assessor were blind to intervention condition (note: double-blinding behavioral and many nonpharmacological treatment and control conditions is rarely, if ever, practical or possible) [C9, C11a, C11b]	
		(e) duration of baseline and outcome assessment periods, treatment periods, and schedule of follow-up assessments	
		(f) eligibility criteria for intervention setting as well as qualifications, training and experience of research staff and practitioners [C3]	
		(g) details of therapeutic interventions sufficient to allow replication (eg, standardization of interventions, tailoring interventions to individuals, when interventions were administered) [C4, C4a, C4b]	
		(h) how treatment integrity was assessed or enhanced [C4c]	
		(i) details of any concomitant medication and dietary supplement use	
		(j) clearly defined primary and secondary outcome measures (including details of reliability and validity) [C6]	
		(k) daily headache diary as principal measure for assessing treatment outcome; report of multiple headache variables (eg, intensity, duration) that includes a measure of headache frequency	
		(l) standardized measures of disability, functional status, and/or “quality of life” to include at least one headache-specific measure	
		(m) statistical methods presented in sufficient detail to allow replication [C12]	
		(n) oversight by institutional review board or equivalent ethics committee	
Results	5	(a) flow of patients through each stage of study (flow diagram recommended[2]) including number of patients assessed, enrolled, allocated to each condition, treated by each center or care provider, lost to follow-up, and included in each analysis [C13, C16]	
		(b) dates defining periods of recruitment and follow-up [C14]	
		(c) baseline clinical characteristics and demographics by condition, center, and care provider [C15]	
		(d) findings for primary and secondary outcome measures by condition [C17]	
		(e) “intention-to-treat”[4] as well as “completer”[5] analyses for principal dependent	

		measures (at a minimum) [C16, C18]	
		(f) optimal reporting of statistics (eg, choice of test, effect size, n/df, variance, significance level and value)[6]	
		(g) treatment responder rate by condition (i.e., proportion of patients deemed "clinically improved")	
		(h) adverse events by condition; whether or not an adverse event led to discontinuation of treatment [C19]	
Discussion	6	(a) key findings with reference to research objectives and hypotheses [C20]	
		(b) conservative interpretation of results in the context of extant literature; implications of findings and their generalizability (external validity) [C21, C22]	
		(c) study limitations [C20]	
Other	7	(a) specify sources of financial and other important support for the research	
		(b) disclose potential conflicts of interest	

Version 1.1, January, 2008

[1]Penzien DB, Andrasik F, Freidenberg BM, Houle TT, Lake AE, Lipchik GL, Holroyd KA, Lipton RB, McCrory DC, Nash JM, Nicholson RA, Powers SW, Rains JC, Wittrock DA. Guidelines for trials of behavioral treatments for recurrent headache, first edition: American Headache Society Behavioral Clinical Trials Workgroup. *Headache*. 2005;45:S109-31. Checklist developed by Donald B. Penzien, PhD, Timothy T. Houle, PhD, Jeanetta C. Rains, PhD, and Jason L. Roberts, PhD.

[2]Number in brackets represents a parallel item in the *Consort Statement 2001 Checklist* and extension to nonpharmacologic treatment (Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P; CONSORT Group. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008 Feb 19;148(4):295-309; Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P; CONSORT Group. Methods and processes of the CONSORT Group: example of an extension for trials assessing nonpharmacologic treatments. Ann Intern Med. 2008 Feb 19;148(4):W60-6).

[3]Headache Classification Subcommittee of the International Headache Society. The international classification of headache disorders (2nd Ed.). Cephalalgia. 2004;24(suppl. 1):1-160.

[4]A strategy for analysis of data in which all participants are included in the group to which they were assigned whether or not they completed the intervention given to the group.

[5]A strategy for analysis of data in which only participants who completed a particular phase or the entire intervention are included in the analysis of group data.

[6]See statistical reporting checklists in Houle TT & Penzien DB. Statistical reviewing for *Headache*. *Headache*. February 2009.

Once you have completed this checklist, please save a copy and upload it as part of your submission. When requested to do so as part of the upload process, please select the file type: *Checklist*. You will NOT be able to proceed with submission unless the checklist has been uploaded. Please DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.