

Page numbers for “Increased Mortality with Sedative-Hypnotics: Unsafe At Any Dose?”
 BMJ.2011.001445, refer to the pages of the 53-page *.PDF file uploaded on October 8, 2011.

STROBE statement checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract		
		(a) Indicate the study's design with a commonly used term in the title or the abstract page 3, line 15
	1	(b) Provide in the abstract an informative and balanced summary of what was done and what was found page 3, but note that the web site restricted abstracts to 250 words, when BMJ instructions elsewhere allow a longer abstract for research reports.
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported page 5
Objectives	3	State specific objectives, including any prespecified hypotheses Page 5-6, the hypotheses that deaths and cancers would be associated with hypnotic use was being replicated, but no superiority of zolpidem to other hypnotics was hypothesized.
Methods		
Study design	4	Present key elements of study design early in the paper pages 6-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Page 6
Participants	6	(a) <i>Cohort study</i> ? Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Page 6 <i>Case-control study</i> ? Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross sectional study</i> ? Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> ? For matched studies, give matching criteria and number of exposed and unexposed Pages 6-7 <i>Case-control study</i> ? For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Covariate categories are in Table 1, pages 22-23. Confounders are defined in Supplementary Table 2, page 37-38.

	Item No	Recommendation
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group Page 6 and Page 36.
Bias	9	Describe any efforts to address potential sources of bias Page 6-7, 9, 37-38, table 7 page 41.
Study size	10	Explain how the study size was arrived at Page 6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why (a) Describe all statistical methods, including those used to control for confounding page 7-8, pages 37-8 (b) Describe any methods used to examine subgroups and interactions 13 tables and 3 figures describe subgroups and interactions
Statistical methods	12	(c) Explain how missing data were addressed Table 1, pages 22-23, shows that data-missing were entered as a separate category in Cox Models. (d) <i>Cohort study?</i> If applicable, explain how loss to follow-up was addressed page 35 <i>Case-control study?</i> If applicable, explain how matching of cases and controls was addressed <i>Cross sectional study?</i> If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses page 43 and numerous tables
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study?eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed Pages 6-7 (b) Give reasons for non-participation at each stage Pages 6-7 (c) Consider use of a flow diagram (a)Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders pages 23-27
Descriptive data	14*	(b) Indicate number of participants with missing data for each variable of interest pages 23-25 (c) <i>Cohort study?</i> Summarise follow-up time (eg average and total amount) page 23
Outcome data	15*	<i>Cohort study?</i> Report numbers of outcome events or summary

	Item No	Recommendation
		measures over time page 23, 30, 39, 43, 45, 47
		<i>Case-control study?</i> Report numbers in each exposure category, or summary measures of exposure
		<i>Cross sectional study?</i> Report numbers of outcome events or summary measures
Main results	16	(a) Report the numbers of individuals at each stage of the study?eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed page 6-7 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Other analyses	17	Report other analyses done?eg analyses of subgroups and interactions, and sensitivity analyses throughout
Discussion		
Key results	18	Summarise key results with reference to study objectives pages 10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias 11, 13-14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence pages 14-15
Generalisability	21	Discuss the generalisability (external validity) of the study results pages 33-34
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based page 15, lines 9-10

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross sectional studies.

The STROBE checklist is best used in conjunction with the explanation and elaboration article.¹⁸⁻²⁰ This article and separate versions of the checklist for cohort, case-control, and cross sectional studies are available at www.strobe-statement.org