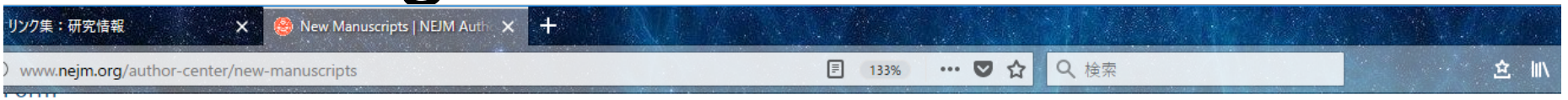
In the textbook of medical statistics...

- A study that is too small may be unethical, since it is not powerful enough to demonstrate a worthwhile correlation or difference.
- Similarly, a study that is too large may also be unethical since one may be giving people a treatment that could already have been proven to be inferior.
- Many journals now have checklists that include a question on whether the process of determining sample size is included in the method section (and to be reassured that it was carried out before the study and not in retrospect).
- The statistical guidelines for the *British Medical Journal* in Altman et al. (2000) state that: **`Authors should include information on … the number of subjects studied and why that number of subjects was used.'**

New England Journal of Medicine



closure Form

ıs of Identifiable Patients

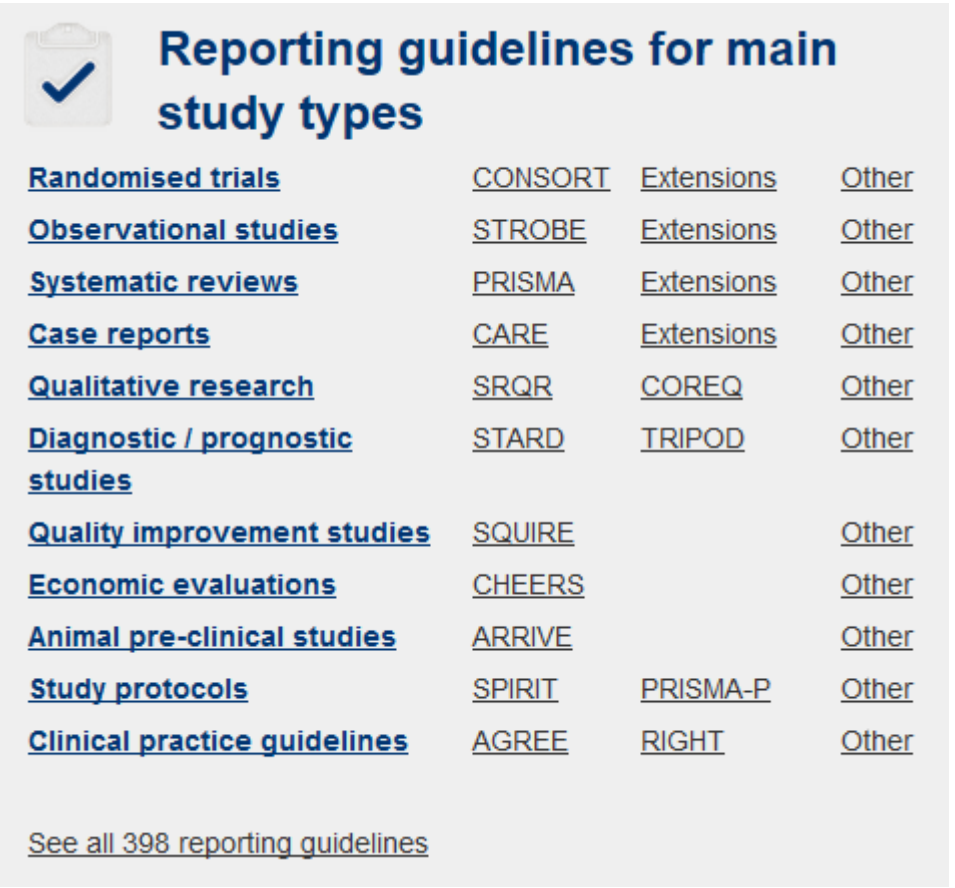
Guidelines for Statistical Methods

Our Statistical Consultants recommend the following best practices with respect to manuscripts submitted to the *Journal*. We recommend that you follow them in the design and reporting of research studies.

- For clinical trials, original and final protocols and statistical analysis plans (SAP) should be submitted along with the manuscript, as well as a table of amendments made to the protocol or SAP indicating the date of the change and its content.
- The primary analyses in manuscripts of clinical trials should match the analyses pre-specified in the original protocol, except in unusual circumstances. Analyses that do not conform to the protocol should be justified in the Methods section of the manuscript. The editors may ask for additional analyses that are not specified in the protocol.
- The Methods section of the manuscript should contain a brief description of sample size and power considerations for the design, as well as a brief description of the methods for primary analysis.
- The Statistical Analysis section of all Methods sections should include a description of the method used to adjust for missing data. For analyses of clinical trials with missing data, please see Ware et al.
- Except when one-sided tests are required by study design, such as in noninferiority trials, all reported P values should be two-sided. In general, P values larger than 0.01 should be reported to two decimal places, and those between 0.01 and 0.001 to three decimal places; P values smaller than 0.001 should be reported as P<0.001. Notable

In commonly adopted guidelines...

- STROBE Statement for Observational Study
  https://strobe-statement.org/fileadmin/Strobe/uploads/checklists/STROBE_checklist_v4_combined.pdf
  "10 Explain how the study size arrive at"
- CONSORT Statement for Clinical Trials
  http://www.consort-statement.org/
  "7a How sample size was determined"
  "7b When applicable, explanation of any interim analyses and stopping guidelines"
- See, EQUATOR
  http://www.equator-network.org/
  which gives summary information of many guidelines



Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions	Other
Observational studies	STROBE	Extensions	Other
Systematic reviews	PRISMA	Extensions	Other
Case reports	CARE	Extensions	Other
Qualitative research	SRQR	COREQ	Other
Diagnostic / prognostic studies	STARD	TRIPOD	Other
Quality improvement studies	SQUIRE		Other
Economic evaluations	CHEERS		Other
Animal pre-clinical studies	ARRIVE		Other
Study protocols	SPIRIT	PRISMA-P	Other
Clinical practice guidelines	AGREE	RIGHT	Other