Item 24. Where the full trial protocol can be accessed, if available

Example—“Full details of the trial protocol can be found in the Supplementary Appendix, available with the full text of this article at [www.nejm.org](http://www.nejm.org).”

Explanation—A protocol for the complete trial (rather than a protocol of a specific procedure within a trial) is important because it pre-specifies the methods of the randomised trial, such as the primary outcome (see item 6a). Having a protocol can help to restrict the likelihood of undeclared post hoc changes to the trial methods and selective outcome reporting (see item 6b). Elements that may be important for inclusion in the protocol for a randomised trial are described elsewhere. There are several options for authors to consider ensuring their trial protocol is accessible to interested readers. As described in the example above, journals reporting a trial’s primary results can make the trial protocol available on their web site. Accessibility to the trial results and protocol is enhanced when the journal is open access. Some journals (such as Trials) publish trial protocols, and such a publication can be referenced when reporting the trial’s principal results. Trial registration (see item 23) will also ensure that many trial protocol details are available, as the minimum trial charac‑ teristics included in an approved trial registration database includes several protocol items and results (www.who.int/ ictrp/en). Trial investigators may also be able to post their trial protocol on a website through their employer. Whatever mechanism is used, we encourage all trial investigators to make their protocol easily accessible to interested readers.