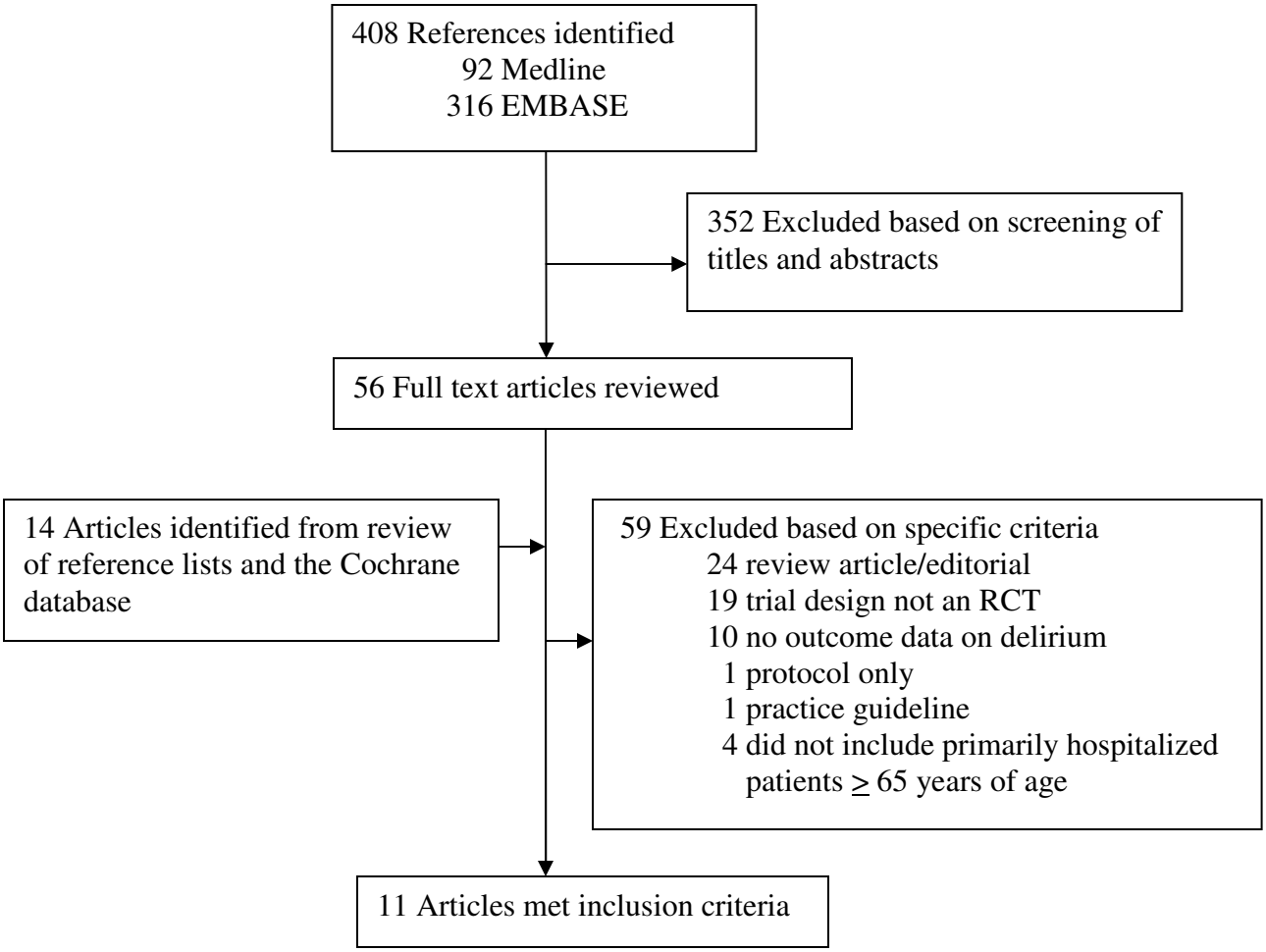**Appendix 2: Study flow** (as supplied by the authors)