Item 13b. For each group, losses and exclusions after randomisation, together with reasons Examples—“There was only one protocol deviation, in a woman in the study group. She had an abnormal pelvic measurement and was scheduled for elective caesarean sec‑ tion. However, the attending obstetrician judged a trial of labour acceptable; caesarean section was done when there was no progress in the first stage of labour.”

“The monitoring led to withdrawal of nine centres, in which existence of some patients could not be proved, or other serious violations of good clinical practice had occurred.”198 Explanation—Some protocol deviations may be reported in the flow diagram (see item 13a)—for example, participants who did not receive the intended intervention. If participants were excluded after randomisation (contrary to the inten‑ tion-to-treat principle) because they were found not to meet eligibility criteria (see item 16), they should be included in the flow diagram. Use of the term “protocol deviation” in published articles is not sufficient to justify exclusion of participants after randomisation. The nature of the protocol deviation and the exact reason for excluding participants after randomisation should always be reported.