Item 11a. If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

Examples—“Whereas patients and physicians allocated to the intervention group were aware of the allocated arm, outcome assessors and data analysts were kept blinded to the allocation.”

“Blinding and equipoise were strictly maintained by emphasising to intervention staff and participants that each diet adheres to healthy principles, and each is advocated by certain experts to be superior for long-term weight-loss. Except for the interventionists (dieticians and behavioural psychologists), investigators and staff were kept blind to diet assignment of the participants. The trial adhered to established procedures to maintain separation between staff that take outcome measurements and staff that deliver the intervention. Staff members who obtained outcome measurements were not informed of the diet group assignment. Intervention staff, dieticians and behavioural psychologists who delivered the intervention did not take outcome measurements. All investigators, staff, and participants were kept masked to outcome measurements and trial results.”

Explanation—The term “blinding” or “masking” refers to withholding information about the assigned interventions from people involved in the trial who may potentially be influenced by this knowledge. Blinding is an important safeguard against bias, particularly when assessing subjective outcomes. Benjamin Franklin has been credited as being the first to use blinding in a scientific experiment. He blindfolded participants so they would not know when he was applying mesmerism (a popular “healing fluid” of the 18th century) and in so doing showed that mesmerism was a sham. Based on this experiment, the scientific community recognised the power of blinding to reduce bias, and it has remained a commonly used strategy in scientific experiments. Box 4, on blinding terminology, defines the groups of individuals (that is, participants, healthcare providers, data collectors, outcome adjudicators, and data analysts) who can potentially introduce bias into a trial through knowledge of the treatment assignments. Participants may respond differently if they are aware of their treatment assignment (such as responding more favourably when they receive the new treatment).153 Lack of blinding may also influence compliance with the intervention, use of co-interventions, and risk of dropping out of the trial. Unblinded healthcare providers may introduce similar biases, and unblinded data collectors may differentially assess outcomes (such as frequency or timing), repeat measurements of abnormal findings, or provide encouragement during performance testing. Unblinded outcome adjudicators may differentially assess subjective outcomes, and unblinded data analysts may introduce bias through the choice of analytical strategies, such as the selection of favourable time points or outcomes, and by decisions to remove patients from the analyses. These biases have been well documented. Blinding, unlike allocation concealment (see item 10), may not always be appropriate or possible. An example is a trial comparing levels of pain associated with sampling blood from the ear or thumb. Blinding is particularly important when outcome measures involve some subjectivity, such as assessment of pain. Blinding of data col‑ lectors and outcome adjudicators is unlikely to matter for objective outcomes, such as death from any cause. Even then, however, lack of participant or healthcare provider blinding can lead to other problems, such as differential attrition. In certain trials, especially surgical trials, blinding of participants and surgeons is often difficult or impossible, but blinding of data collectors and outcome adjudicators is often achievable. For example, lesions can be photographed before and after treatment and assessed by an external observer. Regardless of whether blinding is possible, authors can and should always state who was blinded (that is, participants, healthcare providers, data collectors, and outcome adjudicators). Unfortunately, authors often do not report whether blinding was used. For example, reports of 51% of 506 trials in cystic fibrosis, 33% of 196 trials in rheumatoid arthritis, and 38% of 68 trials in dermatology did not state whether blinding was used. Until authors of trials improve their reporting of blinding, readers will have difficulty in judging the validity of the trials that they may wish to use to guide their clinical practice. The term masking is sometimes used in preference to blinding to avoid confusion with the medical condition of being without sight. However, “blinding” in its methodological sense seems to be understood worldwide and is acceptable for reporting clinical trials.