4.8: Data handling

8.1 Data collection

A necessary part of most trials will be the collection of baseline (pre-intervention) data. These will include identification information on participants, such as name, age, sex, place of residence, and information on other factors that may influence the risk of occurrence of the outcome measures under study in the trial. Although randomization of a large enough number of individuals, or clusters of individuals, should result in an approximately equal distribution of all the important characteristics between trial arms, such baseline data, which should ideally include all known confounders, can be used to check that this balance has actually occurred in practice. And if it has not, then it can also be used to adjust for such imbalances in the trial analyses.

In addition, it may be important to collect general baseline data on the population where the trial is being carried out. These may include not only the epidemiological characteristics of the population, but also the socio-economic, cultural, political, health services, nutritional, and other relevant characteristics. Such contextual factors may be essential to interpreting whether the trial’s results can be generalized to another setting.

Additional data will be collected during the course of the trial to monitor the application of the interventions and to record information on the outcomes of interest. The conduct of a population census is described in Chapter 10, and methods to obtain high-quality data at the start of a trial and during its course are described in Chapter 14. Obtaining data using social or behavioural methods is outlined in Chapter 15, and for measuring the costs of the interventions is outlined in Chapter 19. Of crucial importance in any trial is the proper measurement of the incidence of endpoints against which the intervention is designed to protect, and these aspects are discussed in Chapter 12.
8.2 Data processing

Methods of coding, entering, and then managing computerized data collected in a trial are described in Chapter 20.