#### Item 18: STUDY CHARACTERISTICS.

For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.

**Examples.** In text:

“Characteristics of included studies

Methods

All four studies finally selected for the review were randomised controlled trials published in English. The duration of the intervention was 24 months for the RIO-North America and 12 months for the RIO-Diabetes, RIO-Lipids and RIO-Europe study. Although the last two described a period of 24 months during which they were conducted, only the first 12-months results are provided. All trials had a run-in, as a single blind period before the randomisation.

Participants

The included studies involved 6625 participants. The main inclusion criteria entailed adults (18 years or older), with a body mass index greater than 27 kg/m2 and less than 5 kg variation in body weight within the three months before study entry.

Intervention

All trials were multicentric. The RIO-North America was conducted in the USA and Canada, RIO-Europe in Europe and the USA, RIO-Diabetes in the USA and 10 other different countries not specified, and RIO-Lipids in eight unspecified different countries.

The intervention received was placebo, 5 mg of rimonabant or 20 mg of rimonabant once daily in addition to a mild hypocaloric diet (600 kcal/day deficit).

Outcomes

Primary

In all studies the primary outcome assessed was weight change from baseline after one year of treatment and the RIO-North America study also evaluated the prevention of weight regain between the first and second year. All studies evaluated adverse effects, including those of any kind and serious events. Quality of life was measured in only one study, but the results were not described (RIO-Europe).

Secondary and additional outcomes

These included prevalence of metabolic syndrome after one year and change in cardiometabolic risk factors such as blood pressure, lipid profile, etc.

No study included mortality and costs as outcome.

The timing of outcome measures was variable and could include monthly investigations, evaluations every three months or a single final evaluation after one year.”

#### Explanation.

For readers to gauge the validity and applicability of a systematic review's results, they need to know something about the included studies. Such information includes PICOS ([Box 2](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000100#pmed-1000100-box002)) and specific information relevant to the review question. For example, if the review is examining the long-term effects of antidepressants for moderate depressive disorder, authors should report the follow-up periods of the included studies. For each included study, authors should provide a citation for the source of their information regardless of whether or not the study is published. This information makes it easier for interested readers to retrieve the relevant publications or documents.

Reporting study-level data also allows the comparison of the main characteristics of the studies included in the review. Authors should present enough detail to allow readers to make their own judgments about the relevance of included studies. Such information also makes it possible for readers to conduct their own subgroup analyses and interpret subgroups, based on study characteristics.

Authors should avoid, whenever possible, assuming information when it is missing from a study report (e.g., sample size, method of randomization). Reviewers may contact the original investigators to try to obtain missing information or confirm the data extracted for the systematic review. If this information is not obtained, this should be noted in the report. If information is imputed, the reader should be told how this was done and for which items. Presenting study-level data makes it possible to clearly identify unpublished information obtained from the original researchers and make it available for the public record.

Typically, study-level characteristics are presented as a table as in the example in [Table 2](http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000100#pmed-1000100-t002). Such presentation ensures that all pertinent items are addressed and that missing or unclear information is clearly indicated. Although paper-based journals do not generally allow for the quantity of information available in electronic journals or Cochrane reviews, this should not be accepted as an excuse for omission of important aspects of the methods or results of included studies, since these can, if necessary, be shown on a Web site.

Following the presentation and description of each included study, as discussed above, reviewers usually provide a narrative summary of the studies. Such a summary provides readers with an overview of the included studies. It may for example address the languages of the published papers, years of publication, and geographic origins of the included studies.

The PICOS framework is often helpful in reporting the narrative summary indicating, for example, the clinical characteristics and disease severity of the participants and the main features of the intervention and of the comparison group. For non-pharmacological interventions, it may be helpful to specify for each study the key elements of the intervention received by each group. Full details of the interventions in included studies were reported in only three of 25 systematic reviews relevant to general practice.