and Wee et al. (56) provide fine examples of CONSORT diagrams. This type of flow chart is also called a disposition diagram (57).

The CONSORT statement, which has been revised every few years, is the product of a group which describes itself as an international group of managers of clinical trials and medical journal editors (58). The CONSORT statement, which consists of a checklist of items to be addressed, was developed to improve poor reporting in the context of clinical trials.

b. Reasons for using modified ITT analysis

The following bullet points outline reasons for defining a modified ITT group, and for using modified ITT analysis. As compared to the ITT group, the modified ITT group can exclude:

- Study subjects who withdrew their consent
- Study subjects who failed to receive any study drug
- Study subjects who met the definition of a certain subgroup
- Study subjects who dropped out because of toxicity of the study drug
- Study subjects who were given the wrong treatment by the health care provider
- Study subjects who failed to receive study drug long enough to have a measurable effect
- Study subjects who violated certain aspects of the Clinical Study Protocol, e.g. by taking prohibited drugs
- Study subjects who were determined, after enrollment, not to have met the inclusion criteria or exclusion criteria.

c. Excluding subjects who failed to meet inclusion or exclusion criteria, or who failed to receive study drug – the Vaira study

In a study of *Helicobacter* infections by Vaira et al. (59) modified ITT analysis was used to exclude five subjects, out of the 300 subjects enrolled in the study. One of the subjects was found not to meet the criteria for *Helicobacter* infection at baseline, while four did not receive any study medication. These patients did not receive study medication because one patient developed severe abdominal pain and had cholecystectomy the day after the baseline visit, one patient discovered that she was pregnant before commencing therapy, one patient elected not to take study medications after randomization, and one patient

[56] Wee J, Tan EH, Tai BC, et al. Randomized trial of radiotherapy versus concurrent chemoradiotherapy followed by adjuvant chemotherapy in patients with American Joint Committee on Cancer/International Union against cancer stage III and IV nasopharyngeal cancer of the endemic variety. *J Clin Oncol*. 2005;23:6730–6738.

[57] Fidias PM, Dakhil SR, Lyss AP, et al. Phase III study of immediate compared with delayed docetaxel after front-line therapy with gemcitabine plus carboplatin in advanced non-small-cell lung cancer. *J Clin Oncol*. 2009;27:591–598.

[58] www.consort-statement.org (quotation acquired on February 27, 2011).

[59] Vaira D, Zullo A, Vakil N, et al. Sequential therapy versus standard triple-drug therapy for *Helicobacter pylori* eradication. *Ann Intern Med*. 2007;146:556–563.