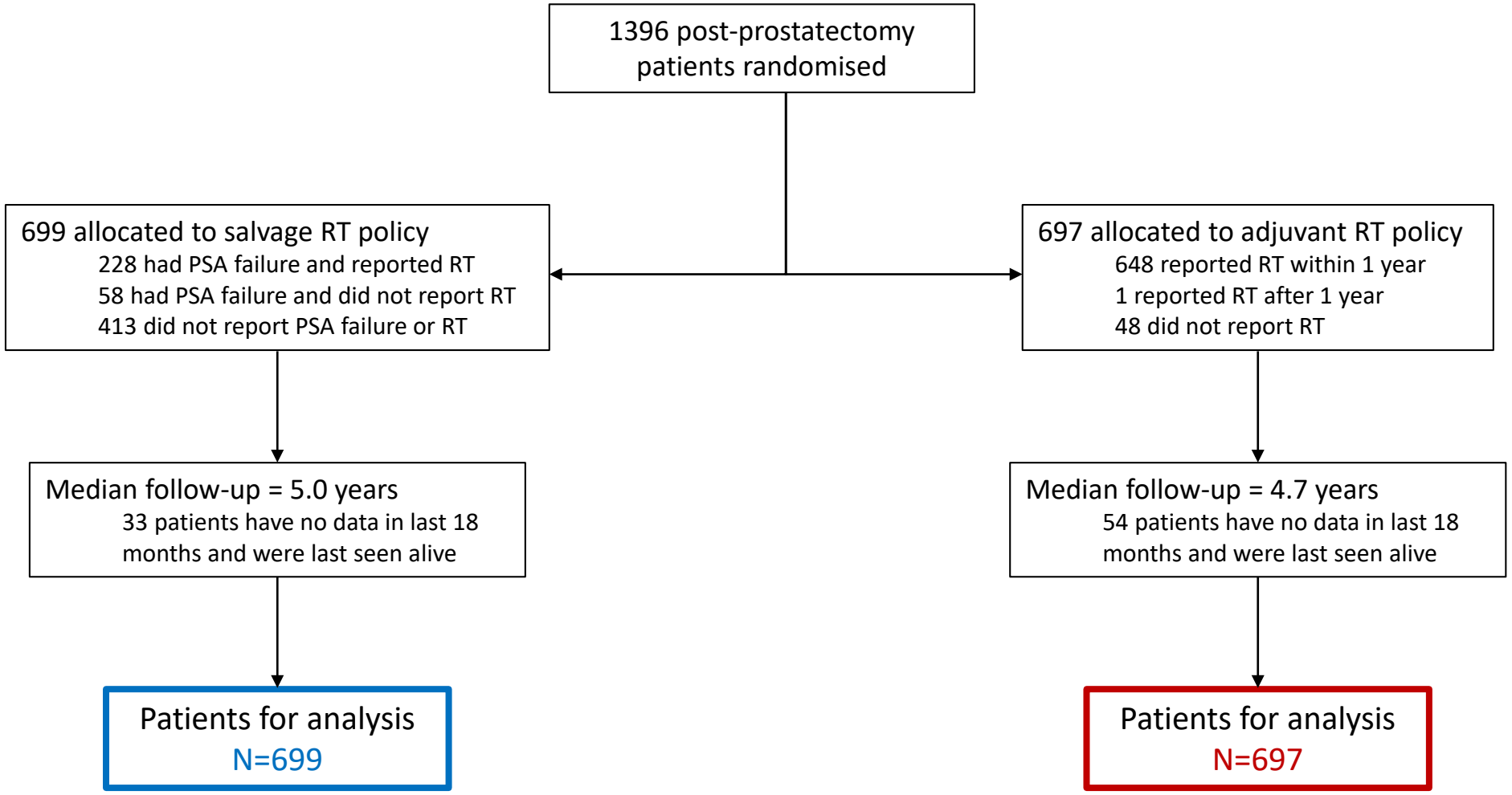Figure 1. CONSORT diagram