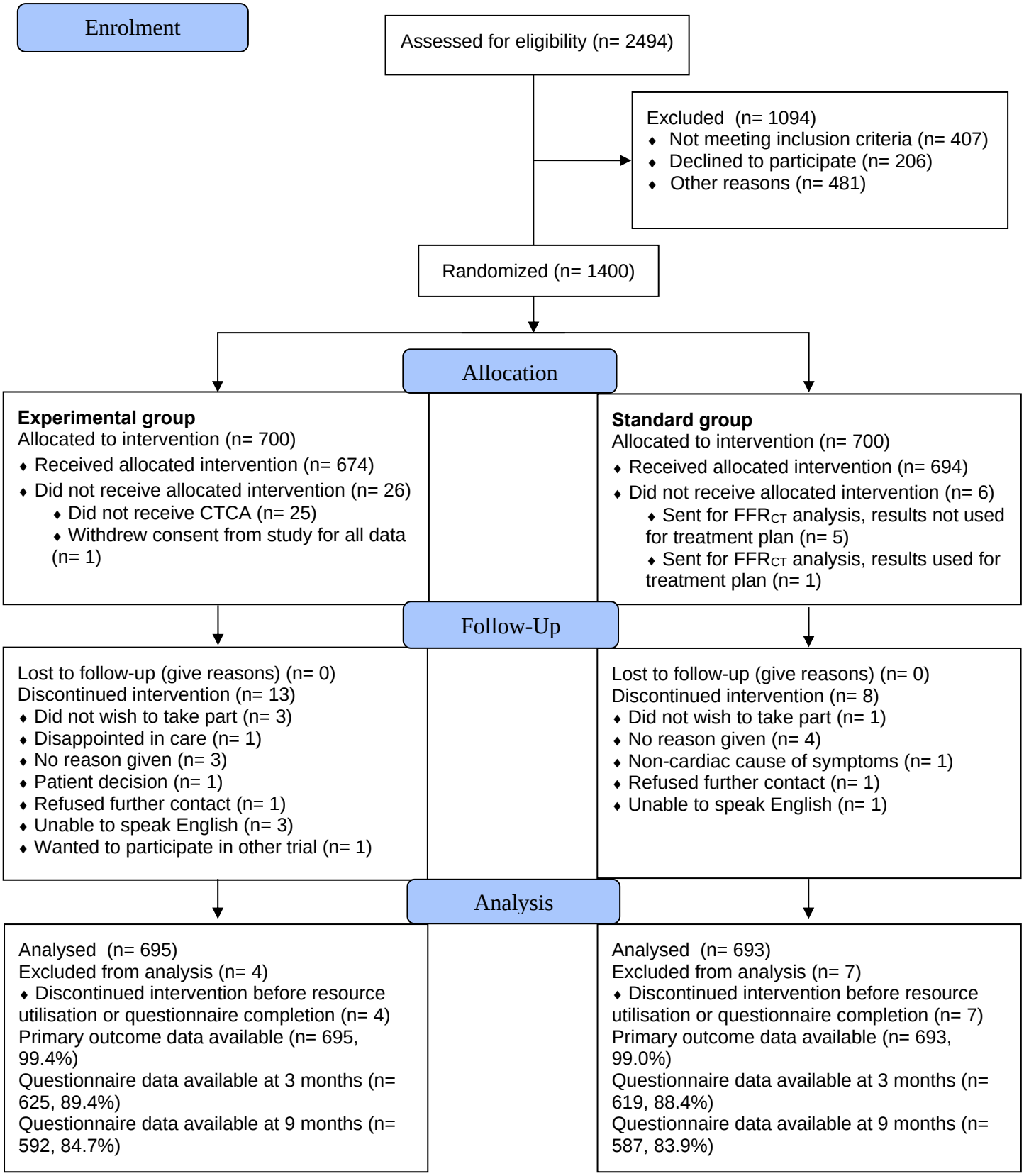Figure 1 – CONSORT Diagram