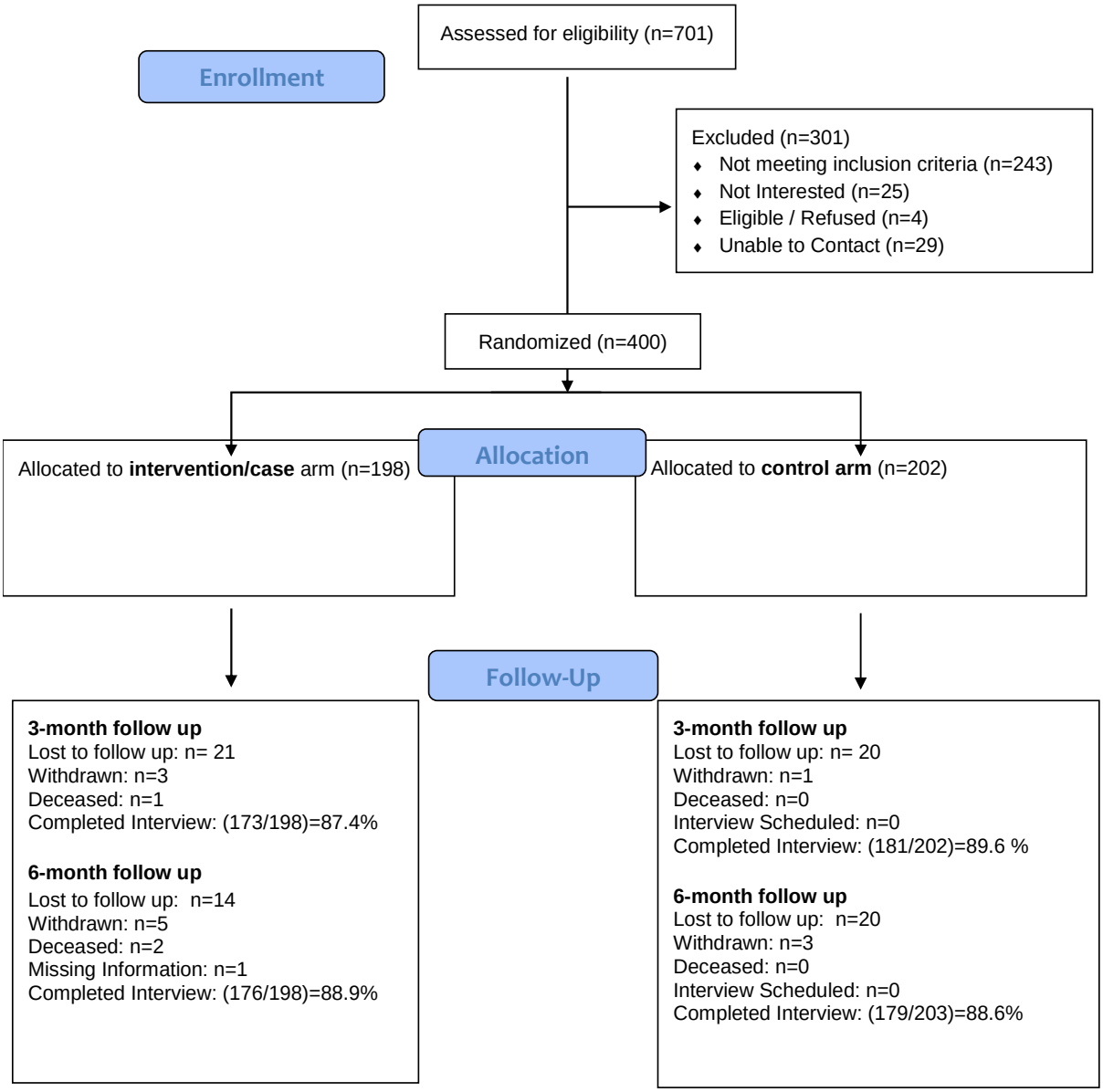Figure 1: CONSORT Flow Diagram