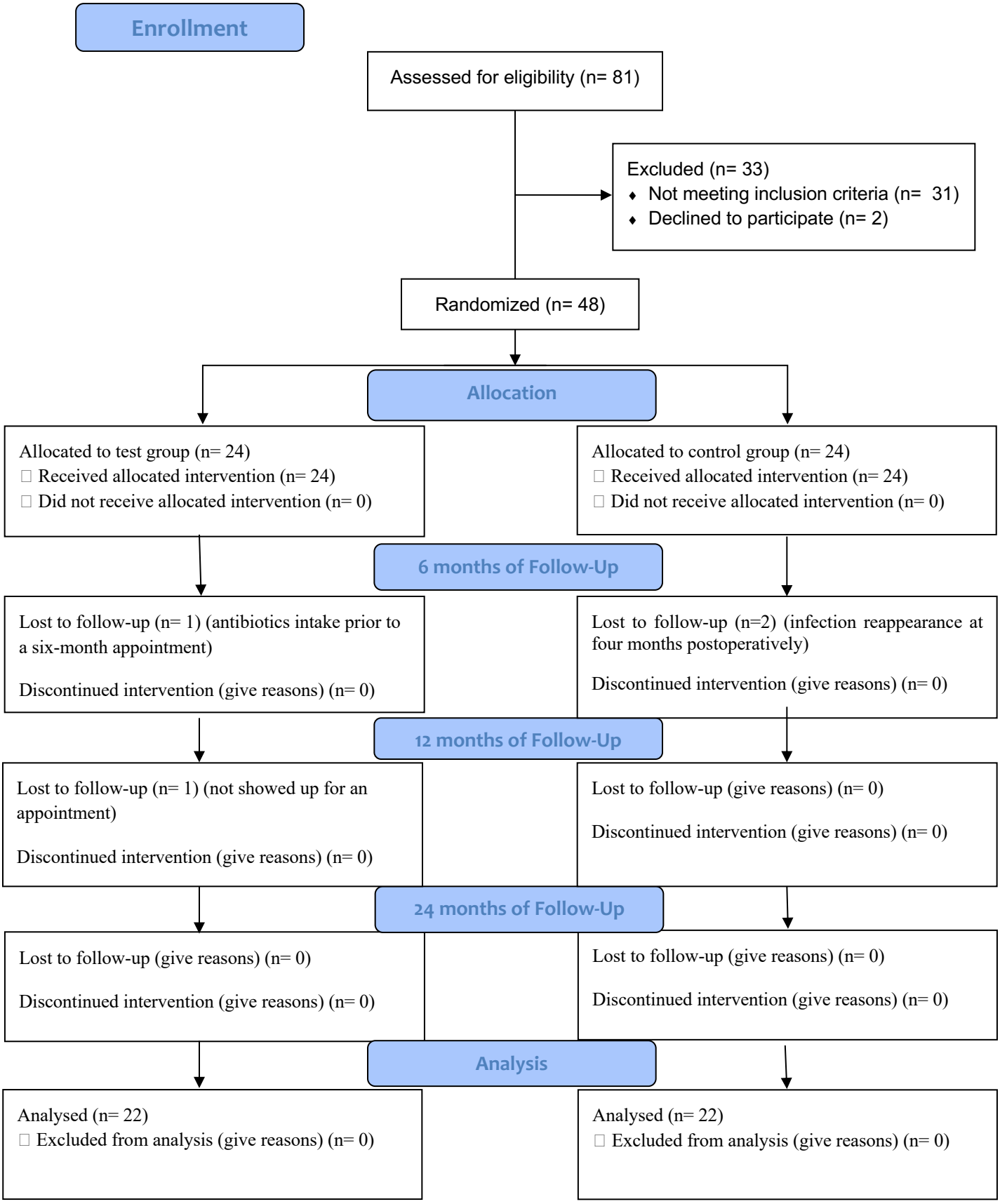CONSORT 2010 Flow Diagram