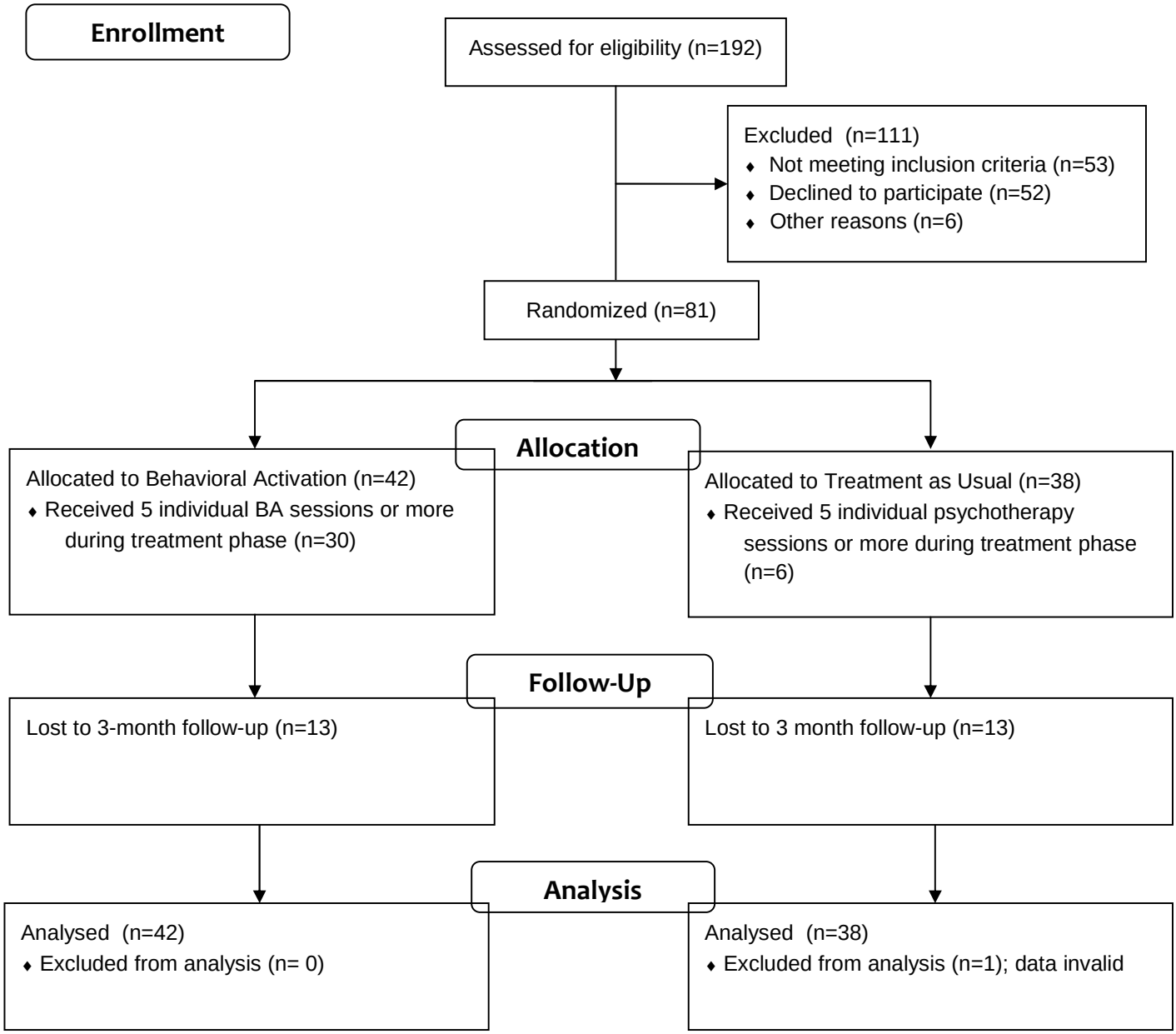CONSORT Flow Diagram