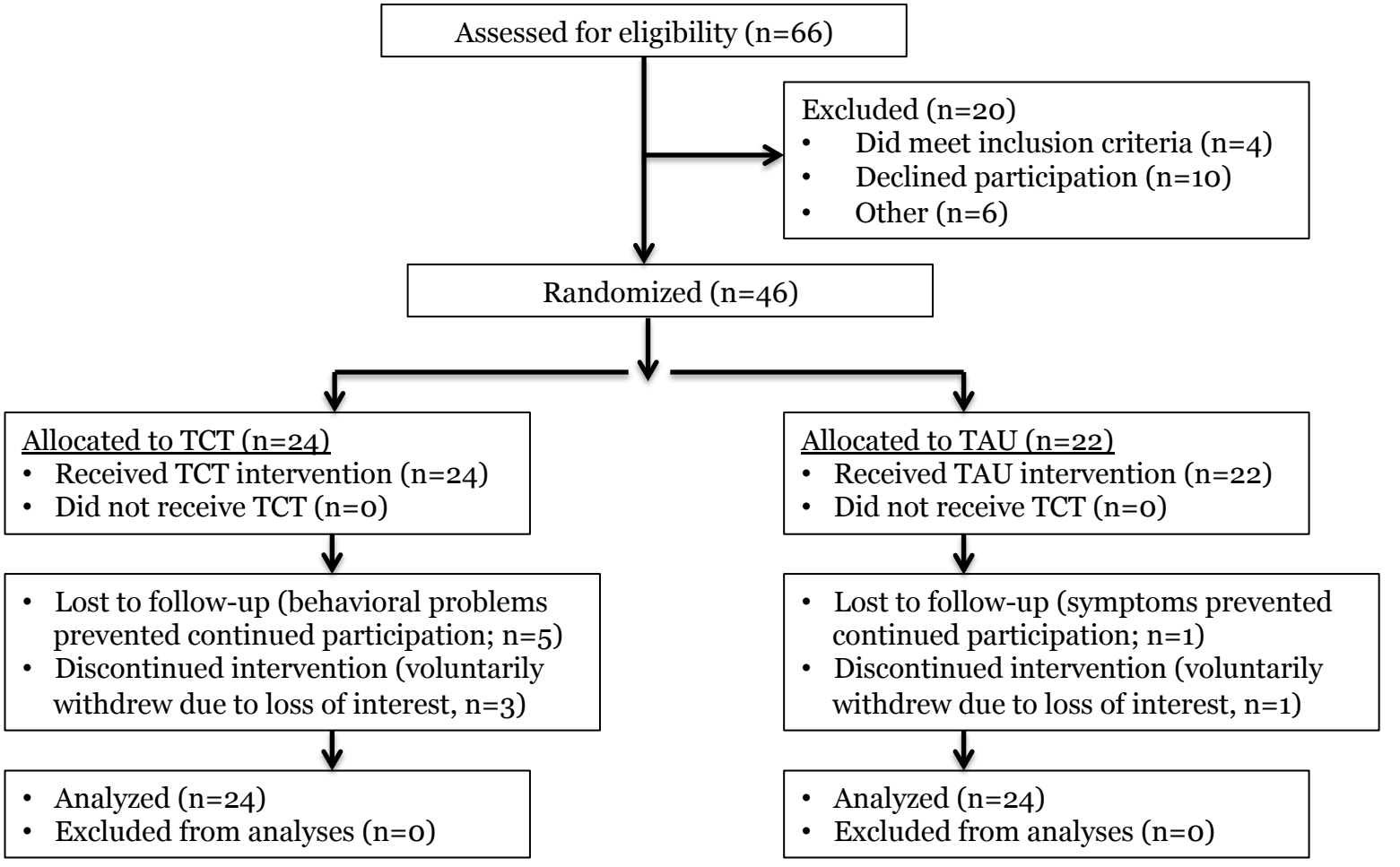CONSORT DIAGRAM